

CLARITY ON PRODUCT-BY-PROCESS PATENTS



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US Patent Law clarified: The confusion and uncertainty surrounding the infringement of 'product-by-process' and 'product-formed-by-process' patent claims has been eased. On May 18, 2009, the US Court of Appeals for the Federal Circuit finally resolved the question as to whether such claims can be infringed by products made by a process other than that claimed. Following the case of *Abbott Laboratories v. Sandoz*, US courts will now no longer find such claims to be infringed unless the claimed process, and no other, is used.

Novel Processes: Many patentable inventions reside in the novel industrial processes used to make products. Examples include composites, metals, plastics and ceramics commonplace in aerospace, automotive, dental, sporting goods and marine applications. Products imported into and sold within the US are often manufactured utilising processes or methods that are, at least in part, performed abroad. In some instances, a single entity may perform all the claimed process steps both abroad and within the US. In others, more than one company may be involved. In the latter instance, the entity performing the last of the series of steps should be able to escape liability by virtue of it not performing all of the claimed steps.

New Ruling: The Federal Circuit's ruling in *Abbott Laboratories v. Sandoz* provides patent attorneys with more certainty on this issue. Where a company has a US patent with one or more product-by-process claims, the steps of the claimed process will profoundly affect enforcement efforts.

The Patent Claim: 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". Now that the Federal Circuit has ruled in the clarifying *Abbott* decision, companies should be better able to avoid patent infringement liability. This may be accomplished by performing within the US fewer than all of the claimed process steps required to produce the claimed product, leaving to others the performance of the remaining claimed process steps.

Example: The following example illustrates this scenario:

- (a) A quick-drying glue applicator is made containing a chemical produced in a series of five sequential process steps
- (b) The first two process steps in producing the chemical are performed by companies W and X in Europe
- (c) Thereafter, the partially made chemical is imported into the US, where the third and fourth process steps are completed by company Y
- (d) The resulting chemical is installed by the fifth process step into the applicator by company Z

"PRODUCTS IMPORTED INTO AND SOLD WITHIN THE US ARE OFTEN MANUFACTURED UTILISING PROCESSES OR METHODS THAT ARE, AT LEAST IN PART, PERFORMED ABROAD."

- (e) There is no corporate relationship or control between and among companies W, X, Y and Z
- (f) Patentee P owns a US patent that includes a product-by-process claim that recites a glue applicator formed by all five process steps
- (g) Patentee P threatens company Z with a lawsuit, alleging infringement of the product-by-process claim
- (h) Company Z promptly seeks an exculpatory opinion from its patent counsel.

Resolution: The *Abbott* decision resolved differing reasoning by two different Federal Circuit panels' decisions. The Federal Circuit in *Scripps Clinic & Research v. Genentech* held that a product-by-process patent claim is not limited by the process steps recited therein. The following year, another Federal Circuit panel in *Atlantic Thermoplastics v. Faytex* held that product-by-process claims only cover products that are produced by the process steps recited in the claim. Under *Abbott*, Company Z should not be liable. Of course, patents often contain different types of claims so that company Z's sales, covered by an article claim, may render it liable under that claim.

Conclusion: Those involved in the preparation and prosecution of US patent claims will be guided by the *Abbott* decision. And those called upon to render right-to-use and non-infringement opinions will find comfort in the Federal Circuit's clarification of the product-by-process issue.

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