Scott B. Familant
is a partner in the New York Office of Orrick, Herrington & Sutcliffe LLP, one of America's pre-eminent, full service intellectual property law firms. His practice focuses primarily on pharmaceutical and biotechnology litigation.

Kinik: Raising the stakes for importing products derived from US patented processes practised abroad

Scott B. Familant

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Abstract

This paper analyses the recent ruling in *Kinik Co. v. Int'l Trade Comm'n,* 362 F.3d 1359 (Fed. Cir. 2004), and the impact that decision may have on proceedings before the US International Trade Commission under the Tariff Act of 1930 (19 USC §1337(a)) – particularly those concerning the importation of products derived from practising US patented processes abroad.

Keywords: *Kinik, importation, 35 USC §271(g), 19 USC §1337(a)(1)(B)(ii)*

INTRODUCTION

Many biotech and pharmaceutical companies have attempted to avoid liability for infringement of US process patents by practising the patented methods (eg methods of plasmid construction, transfection or expression) abroad and thereafter importing into the USA a materially altered form of the resulting product (eg a variant of a cell, protein or plasmid). As discussed below, such conduct is beyond the reach of the US patent laws as applied by federal district courts. However, the recent ruling in *Kinik Co. v. Int'l Trade Comm'n*[1] indicates that such conduct may constitute an unfair trade practice under the Tariff Act of 1930, which is administered and enforced by the International Trade Commission (ITC). Thus, we may very well see an upswing in ITC filings challenging the importation of products manufactured abroad using processes patented in the USA.

THE TARIFF ACT OF 1930: THE ORIGINAL BASIS FOR TREATING IMPORTS PRODUCED BY US PATENTED METHODS AS ACTIONABLE

In 1930, Congress enacted the Smoot–Hawley Tariff Act. Section 337 (19 USC §1337) of the Act was intended to foster fair trade in the USA by making it illegal to import products that injure domestic industries through some form of unfair competition.[2] In 1940, the Act was amended to prohibit the importation of a product manufactured abroad by practising a US patented method. This amendment was Congress's response to and rejection of a judicial decision, *In re Amtorg Trading Corp.*,[3] which refused to recognise such quasi-extraterritorial conduct as giving rise to an act of patent infringement in the USA.[4]

The current provision of the Act that prohibits such activities is 19 USC §1337(a)(1)(B)(ii), which reads:

> (a) Unlawful activities; covered industries; definitions
>
> (1) Subject to paragraph (2),[5] the following are unlawful, and when found by the [ITC] to exist shall be dealt with, in addition to any other provision of law, as provided in this section:
>
> (B) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner,

Scott B. Familant
Orrick, Herrington & Sutcliffe LLP,
666 Fifth Avenue,
New York, NY 10103, USA

Tel: +1 212 506 5000
Fax: +1 212 506 5151
E-mail: sfamilant@orrick.com

importer, or consignee, of articles that

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(ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

Prior to 1989, this statute was the only basis for seeking redress for the importation of products made abroad by practising a process patented in the USA. Moreover, this remedy has been limited to US patent holders who can prove that a domestic industry relating to the products at issue exists or is in the process of being established in the USA. Thus when a domestic industry was implicated, US patent holders could petition the ITC for an exclusion order banning the importation of such products.[6]

THE PROCESS PATENT AMENDMENTS ACT OF 1988: A SEPARATE BASIS FOR PROHIBITING IMPORTS PRODUCED BY US PATENTED METHODS

In 1988, Congress amended the patent laws to make the importation of a product manufactured abroad by a US patented method an act of patent infringement. This amendment was intended to bring US patent law in line with the European Patent Convention, the Community Patent Convention and the World Intellectual Property Organisation Treaty on Harmonisation as well as supplement remedies available under Section 1337(a) of Title 19.[7] It is codified at 35 USC §271(g) and reads:

Equitable defences available under the 1930 Tariff Act

Exceptions to 35 USC §271(g)

> Whoever without authority imports into the United States . . . a product which is made by a process patented in the United States shall be liable as an infringer, if the importation . . . occurs during the term of such process patent . . ..

After the enactment of this provision, a patentee had a second forum before which it could potentially seek redress for the importation of products manufactured abroad by use of US patented processes. Accordingly, an action could now be brought in federal district court seeking not only injunctive relief (the principal form of relief available in the ITC), but also damages.[8] Unlike the Tariff Act, proof of a domestic industry relating to the products at issue was not required. Therefore, §271(g) could pose a barrier for importing products for which no domestic industry exists or is being created.

THE QUESTION RAISED IN *KINIK*: ARE BOTH STATUTES CO-EXTENSIVE IN DEFINING AN INFRINGING IMPORT?

Subsections 1–2 of Section 271(g) codify two exceptions that insulate the importation of certain products from patent infringement liability 'for the purposes of this title': (1) the product manufactured by the patented process was subsequently 'materially changed' before being imported; or (2) the product manufactured by the patented process became 'a trivial and non-essential component' of the imported product.[9]

Section 1337(c) of the 1930 Tariff Act indicates that, with respect to proceedings under Section 1337, '[a]ll legal and equitable defenses may be presented . . .'. One might have assumed from this language that the defenses codified in Section 271(g)(1)–(2) would apply with equal force in ITC proceedings under Section 1337. *Kinik*, however, indicates otherwise. Despite the foregoing language of Section 1337(c), the Court of Appeals for the Federal Circuit gave controlling effect to the text of Section 271(g), the legislative history underlying that statute, and precedent (including precedent

giving deference to the ITC as the agency charged with Section 1337's administration). Focusing on the language of Section 271(g), the court noted that the clause introducing subsections (1)–(2) expressly limited those defences 'for purposes of this title'.[9] In this regard, the Federal Circuit shared the Commission's view that subjecting Section 1337(a)(1)(B)(ii) to these defences would impermissibly render that quoted language from §271(g) superfluous and thereby violate 'a cardinal principle of statutory construction'.[10]

35 USC §271(g)'s legislative history

The legislative history underlying Section 271(g) also reflects that Congress did not intend to subject Section 1337(a)(1)(B)(ii) to the two exemptions of Section 271(g). Two items in the legislative history were particularly influential to the court's analysis. First, language in the implementing legislation, Public Law 100–418, §9006(c), cautioned that '[t]he amendments made by this subtitle shall not deprive a patent owner of any remedies available . . . under section 337 of the Tariff Act of 1930 . . .'.[11] Secondly, Senate Report No. 100–83, which commented on the Senate's version of the bill, noted (at 60–61) that '[n]either is there any intention for these provisions to limit in any way the ability of process patent owners to obtain relief from the U.S. International Trade Commission'.[12]

Examples where 35 USC §271(g)(1)–(2) were successfully invoked

Thus, *Kinik* underscores that the defenses codified in Section 271(g)(1)–(2) are not cognisable in actions arising under Section 1337(a)(1)(B)(ii).

THE IMPLICATIONS OF *KINIK*: THE ITC AS A PREFERRED VENUE FOR CHALLENGING INFRINGING IMPORTS

The holding in *Kinik* is likely to have significant repercussions for the pharmaceutical and biotech industries. Many companies operating in these fields (particularly those having an international presence) have sought to avoid patent liability by practising US patented processes in a country that has no corresponding protection. The resulting pharmaceutical or biological is then modified with the expectation that such additional processing will 'materially alter' the product in a fashion that qualifies for exemption under Section 271(g)(1) once it is imported into the USA. Indeed, at least two reported cases illustrate the successful implementation of this very strategy.

In *Eli Lilly & Co. v. American Cyanamid Co.*,[13] Lilly held a patent directed to a process for manufacturing a cephem intermediate. American Cyanamid imported the antibiotic cefaclor from an Italian drug company that practised the patented method to form the intermediate and then (with the benefit of additional processing steps) converted that intermediate into cefaclor.[14] The importation of cefaclor did not violate Section 271(g) because the additional processing steps used to convert the intermediate to cefaclor materially changed the intermediate into a compound that had different physical and chemical properties.[15]

Similarly, in *Genentech, Inc. v. Boehringer Mannheim GmbH*,[16] Genentech held a patent directed to a method of manufacturing an expression plasmid for the production of polypeptides. Boehringer conceded that it practised that method abroad to construct an expression plasmid encoding t-PA. This 'intermediate' plasmid, however, was then modified to create production plasmids expressing Reteplase, a truncated t-PA variant lacking a native glycosylation site and having an extended blood half-life.[17] The court found that the additional processing steps Boehringer used to develop the production plasmids were not covered by the patent, and that these intervening steps changed the physical and chemical properties of the intermediate plasmid and its expression product, t-PA, in material ways.[18] Thus, Boehringer '[broke] the chain of infringement under § 271(g).'[19]

Although subsequent processing steps

in these two instances precluded a finding of patent infringement under Section 271(g), the additional steps would likely not provide a defence to an action for unfair competition under Section 137(a)(1)(B)(ii) in light of *Kinik*. Thus, the ITC is an attractive (in some cases, the only) venue for holders of US process patents when there is a risk that an infringer may be able to negate patent infringement in federal district court by invoking the exemptions of Sections 271(g)(1)–(2).

OTHER CONSIDERATIONS FAVOURING THE ITC

Other considerations also make the ITC an attractive alternative to a federal district court. For example, although Section 1337(a) requires an injury to a domestic industry (cf. Section 1337(a)(3)), a number of judicial decisions and legislative amendments have made compliance with this requirement easier to satisfy – especially for foreign companies owning US patents.[20] In addition, for the past several years, ITC proceedings have tended to conclude within 12–15 months, a time frame that is far shorter than that of the average patent litigation in federal district court.[21] Moreover, because its proceedings are largely *in rem*, rather than *in personam* (unlike federal district court patent infringement proceedings), the ITC need not establish personal jurisdiction over foreign manufacturers and importers to issue injunctive orders regarding the importation of a product.[22] Finally, the ITC has the authority to issue exclusion and cease and desist orders that are enforceable by the Customs Service at every port of entry as well by federal district courts.[23] This relief can often have a devastating impact on a defendant's business since it can effectively preclude access to the entire USA, a major market for pharmaceutical and biotech products.

Speedy proceedings, *in rem* jurisdiction and expansive equitable powers favour the ITC as a forum

CONCLUSION

In light of *Kinik*, pharmaceutical and biotechnology companies may be forced to re-evaluate foreign manufacturing strategies that were adopted in order to avoid patent liability in the USA. *Kinik* underscores that Section 1337(a) of Title 19 provides an alternative statutory basis for challenging infringing acts of importation before an administrative forum that has certain advantages over a federal district court.

The views expressed in this paper are those of the author and not necessarily those of the author's firm, others in that firm or its clients. Nothing about this paper should be construed as legal advice or a legal opinion on any particular matter. Each individual case presents its own unique facts that must be carefully analysed in view of current, applicable law before specific legal advice can be rendered.

References and notes

1. 362 F.3d 1359 (Fed. Cir. 2004).
2. Duvall, D. K., McCabe, P. J. and Bateman, J. W. (2003), 'Unfair Competition and the ITC', West, Eagan, MN, §1:2 (hereinafter Duvall).
3. 75 F.2d 826 (CCPA 1935).
4. *See Amgen, Inc., v. United States Int'l Trade Comm'n*, 902 F.2d 1532, 1538 (Fed. Cir. 1990).
5. Paragraph 2 of the statute states that subparagraph (B) of paragraph (1) 'appl[ies] only if an industry in the United States, relating to the articles protected by the patent . . . concerned, exists or is in the process of being established.'
6. *See Kinik*, 362 F.3d at 1362; *see also Amgen*, 902 F.2d at 1537–1540.
7. *See* S. Rep. No. 100-83, at 30–31.
8. *See Kinik*, 362 F.3d at 1362. Civil penalties may also be imposed against one who violates a cease and desist order. *See* 19 USC §1337(f)(2).
9. *See also Kinik*, 362 F.3d at 1362.
10. *Id.* at 1362 (quoting *Duncan v. Walker*, 533 US 167, 174 (2001)).
11. *Id.* (quoting Pub. L. 100-418, §9006).
12. *Id.* at 1363 (quoting S. Rep. No. 100-83, at 60–61).
13. 896 F. Supp. 851 (SD Ind. 1995), *aff'd*, 82 F.3d 1568 (Fed. Cir. 1996).
14. *Id.* at 853–854.
15. *Id.* at 857–859.
16. 47 F. Supp.2d 91 (D. Mass. 1999).

17. *Id*. at 98, 100–104.
18. *Id*. at 112.
19. *Id*. at 111.
20. *See* Duvall §1:10 (discussing, eg, *In re Certain Facsimile Machines*, ITC Inv. No. 337-TA-367, 1995 WL 1049679 (Sept. 1994), in which a Japanese company was the principal complainant).
21. *Accord* Duvall § 1.5.
22. *See* Duvall §§2:21–22. *In personam* jurisdiction, however, may be required before the ITC when the equitable relief sought pertains to restraining acts beyond mere importation or to imposing civil penalties. *See id*. at 2:22 (discussing *In re Large Video Matrix Display Systems*, ITC Inv. No. 337-TA-75, USITC Pub. No. 1158 (1981)).
23. *See* 19 USC §§1337(e)–(g); *see also* Duvall §2:2.