Strategies to strengthen your patent

A novel claim-drafting approach

Brian D Coggio and Eric Brandon Fugett of Fish & Richardson explore a possible way to strengthen US patents with diagnostic assay claims against extraterritorial infringement

The authors propose a novel claim-drafting strategy to strengthen such patents against infringing activity conducted abroad based on the Federal Circuit’s decision in NTP v. Research in Motion.

Section 271(g) does not protect process patents that yield “mere information”

In Bayer AG v. Housey Pharmaceuticals, the Federal Circuit held that section 271(g) does not prohibit the importation of intangible information because such information is not a “product which is made by a [patented] process.” In Bayer, the patents-at-issue were directed to methods of screening for substances that affect protein expression in a cell. Specifically, the patents claimed a method for determining whether a particular substance induced a cell to make more or less of a protein of interest. Housey claimed that Bayer infringed the patents by importing research data obtained using the patented methods into the United States. The Federal Circuit rejected Housey’s argument by construing the term “made” to mean “manufactured”, which requires creation of a physical article. The court further supported its narrow construction by reviewing the legislative history and concluding that “Congress was concerned with tangible products and not mere information.” Thus, the court limited the applicability of section 271(g) to only those processes that produce tangible items, leaving owners of US patents for processes that yield intangible information — such as diagnostic assays — powerless to deter competitors who infringe from abroad.

Additionally, by narrowing section 271(g), Bayer all but created an incentive for extraterritorial infringement of those process patents now excluded from statutory protection. For example, under the Bayer court’s reading of section 271(g), a competitor of the patentee could avoid infringing a patented biological diagnostic assay for determining whether a patient has a specific condition by collecting the requisite human tissue or blood samples locally and sending the samples abroad for analysis using the patented method.

Subsequent importation of the test results, potentially constituting data as simple as a positive or negative determination, would not constitute infringement under section 271(g) because the imported information is not “tangible”. This limitation, combined with the more
traditional economic incentives associated with outsourcing, poses a threat to companies that develop and exploit patents covering diagnostic assays. The threat to the biotechnology industry is particularly striking since many patented processes may yield “mere information.” Moreover, the lack of transportation costs associated with transmission of data into the United States makes such inventions uniquely susceptible to extraterritorial infringement. In a global marketplace, any such foreign activity could potentially impact the domestic market.

The ease with which a potential infringer can threaten local business illustrates the lack of protection available to patents relating to information-yielding processes, particularly diagnostic assays. Although \textit{Bayer} foreclosed section 271(g) as a deterrent against extraterritorial infringement of these types of patented processes, more recent Federal Circuit precedent broadening the scope of section 271(a) may provide patent prosecutors with a solution to this problem by drafting ‘system’ claims.

**System claims can reach extraterritorial infringement**

According to the Federal Circuit’s holding in \textit{NTP, Inc. v. Research in Motion, Ltd. (NTP II)}, system and process claims differ dramatically in their ability to reach overseas activity.” In \textit{NTP II}, the court addressed the scope of section 271(a) as limited by the phrase “uses … within the United States.” Drawing a pronounced distinction between system and method (process) claims, the court held that the use of a claimed system occurs at the place “where the system as a whole is put into service, i.e., the place where control of the system is exercised and beneficial use of the system obtained.” The court then held that “a process cannot be used within the United States … unless each of the steps is performed within this country.” In short, the court broadened the extraterritorial reach of section 271(a) by bifurcating the “use” analysis for the two different claim types.

**A. The situs of use analysis for system claims under section 271(a) looks only to the location where control is exercised and beneficial use obtained**

The relevant patents in \textit{NTP II} contained both system and process claims and related to a remote email system that provided users with wireless mobile email access. The system comprised multiple components, the nature of which allowed their function and use to be separated from their physical location. A necessary component of the accused Blackberry system, operated by Research in Motion, was located in Canada.” The court found that only the system claims were infringed, despite that the non-infringing process operated via the same platform.” The court reasoned that a system claim may be infringed even though all components are not located within the United States because the components of a system are used collectively rather than individually.” Indeed, the court’s only basis for applying different analyses to the process and system claims arose from substitution of the word “system” for “process” in the preambles of the patent claims. Table 1 illustrates the relevant claim language in a simplified format.

<table>
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<tr>
<th>Table 1. Example system and process claims</th>
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<td>System claim: “A system for [X], comprising:”</td>
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<tr>
<td>Process claim: “A process for [X], comprising:”</td>
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Analysis of system claims under \textit{NTP II} focuses on the situs of use of the invention as a whole, rather than the situs of use of each element of the claim.” Specifically, under the “beneficial use and control” test, a Blackberry user located within the United States who directs a handheld device to retrieve email controls the collective system and receives its beneficial use where the device is activated, i.e., in the United States. Thus, such party infringes the system claims in that location. Conversely, under the traditional strict geographic analysis applied to process claims, the same Blackberry user does not infringe the process claims because the claims recite a step using an “interface switch” located in Canada.” Although it might be hailed as a distinction without a difference, the Federal Circuit clearly held the claim language directly controls infringement analysis, and by extension, a patent’s extraterritorial reach.” Thus, location of a system component overseas is not a bar to enforcement of US patents for systems that yield information, like patents covering diagnostic assays, if the situs of use of the system is within the United States.

Two recent district court decisions elucidate how the Federal Circuit’s “beneficial use and control” test has been applied to identify the situs of use. The patent in \textit{Renhold Inc. v. Don Best Sports} was directed to an electronic marketplace for obtaining prediction information.” The accused websites were designed so that US visitors interacted with the sites by remotely executing codes housed on foreign computers.” The court interpreted the situs of use to include the place where the system was “effectively controlled and where the benefits flowed.” Finding that the situs of use was in the United States, the court reasoned that local prediction information providers and users exercised effective control when they uploaded and downloaded data by executing the infringing code. The court also found that the benefits from use of the infringing code flowed to persons within the United States as the prediction information users received the requested data and the providers were paid if their predictions proved correct.”

By contrast, the court in \textit{CNET Networks, Inc. v. Ebitize, Inc.} focused its situs of use analysis on the control element.” The claims-at-issue in that case were directed to a system for gathering and aggregating product information from various websites and automatically creating an electronic catalog of the resulting data.” The accused catalogue included information taken from websites located on servers in the United States.” The court granted summary judgment of non-infringement under section 271(a) because “overall control” of the claimed information collection process and catalogue creation was not exercised within the United States. The court reasoned that there was only “one component of the system, the whole of which was put into service in Pakistan” because all website visits were “initiated … by [persons] in Pakistan” executed from a server in Pakistan.” and because the data collection and catalogue creation did not occur “dynamically, in response to and only as a result of” a customer requesting a catalogue.

**B. System claims having a diagnostic assay component may be enforceable against extraterritorial infringement of the assay component**

Practically, \textit{NTP II} and its progeny may well close the gap in statutory protection under section 271(g) articulated by \textit{Bayer} and afford certain patentees greater ability to enforce US patents against overseas infringement than ever before. A hypothetical illustrates the potential breadth of protection presented by system claims under \textit{NTP II}. Consider a US patent that covers a test to determine whether a patient has a certain disease, which comprises the following elements: a patient requesting such a determination from a doctor; acquisition of a sample of a biological material from the patient; analysis of the sample using a specified diagnostic assay; and communication of the test results back to the patient (or doctor). Further assume that an unlicensed competitor employs the patented diagnostic assay component of the claim abroad and reports the results back to US patients (doctors).

Under \textit{Bayer}, the hypothetical US patent owner has limited enforcement options to
hypothetical system precludes a finding that regardless of whether a court views the doctor put into service[,]” is in the United States. Thus, the situs of use of the hypothetical application, these benefits could be specifically subsequently receive payment. In drafting an to the doctor include the ability to diagnose treatment may be necessary. Benefits “flowing” the requested medical information. The value use of the patented diagnostic assay person may be viewed as having gained the exercised by a US party, who remotely initiates “overall control” by “initiating” the system upon ordering the testing. Regardless of which result of “the patient’s request. Alternatively , the patient or doctor. Indeed, the patient or doctor is still the party exercising “control” of the system, even if a foreign technician chooses the assay conditions because control over an individual component of the system is not “control” of the system as a whole.” Thus, a court could find that the situs of use of the hypothetical system is the United States. Accordingly, direct infringement would exist under section 271(a) and allegations of induced and contributory infringement could be lodged under sections 271(b) and (c), respectively.

III. Patent prosecutors should draft system and process claims for patents covering inventions that yield information

In conclusion, the Federal Circuit’s decision in NTP II seemingly increased the extraterritorial reach of patent protection available to information-yielding processes by making a distinction between the direct infringement analysis applicable to system and method (process) claims. This distinction may foreclose relocation of an essential system component overseas as a means for potential infringers to avoid liability under US patent laws. While this area of the law is far from settled, NTP II and its progeny indicate that the situs of use of an infringing system is “within the United States” if its components are used collectively rather than individually, and a US party can independently put the system as a whole into service and receive the resulting benefits. Although ‘system’ claims may offer broader protection than process claims, the situs of use analysis applicable to process claims is well understood, and the use of process claims should not cease. Therefore, to secure a patentee the greatest protection possible under the law, patent prosecutors should draft ‘system’ claims broad enough to satisfy the situs of use analysis described in the NTP II line of cases in addition to traditional process claims. Careful consideration to the precise wording of such ‘system’ claims is, of course, necessary.

Notes
1. The terms “method” and “process” are used synonymously herein.
2. The ITC also has jurisdiction to prevent, inter alia, importation of products made by practicing a process covered by U.S. patent. See Title 19, U.S.C., § 1337 (a) (1) (B) (ii). This provision, however, does not solve the situation discussed in this paper.
3. See Bayer AG v. Housey Pharmaceuticals, Inc. 340 F.3d 1367 (Fed. Cir. 2003). 4. See NTP Inc. v. Research in Motion, Ltd., 418 F.3d 1282 (Fed. Cir. 2005) (holding that accused system was used within the United States for purposes of determining whether system claims were infringed even where an element of the accused system was located abroad).
6. Id. at 1369.
7. Id. at 1371-72.
8. Id. at 1376.
10. Id. at 1317.
11. Id. at 1318 (internal quotations omitted).
12. Id. at 1289.
13. Id. at 1313.
14. Id. at 1290.
15. Id. at 1318.
16. “[A] process is nothing more than the sequence of actions of which it is comprised, the use of a process necessarily involves doing or performing each of the steps recited. This is unlike the use of a system as a whole, in which the components are used collectively, not individually.” Id. at 1318.
17. Id. at 1317.
18. Id. at 1318.
19. Id. at 1316.
20. Although Renholc involved apparatus claims rather than ‘system’ claims, the court nevertheless applied NTP II’s “beneficial use and control” test, reasoning that there was no difference between the legal definition of “use” of an infringing system or a device with multiple components used as a whole. 548 F.3d at 356, 358-61 (E.D. Tex. 2008).
21. Id. at 363-64.
22. Id. at 361 (quoting 2 Robert A. Matthews, Jr., Annotated Patent Digest § 10.24 (2008)).
23. Id. at 363-64.
25. Id. at 987-88.
26. Id. at 991.
27. Bayer AG, 340 F.3d at 1371-72.
28. NTP II, 418 F.3d at 1318.
29. Id. at 1317.
30. See 418 F.3d at 1317.
31. Id. at 1313.
32. Id.; 528 F.3d at 991.