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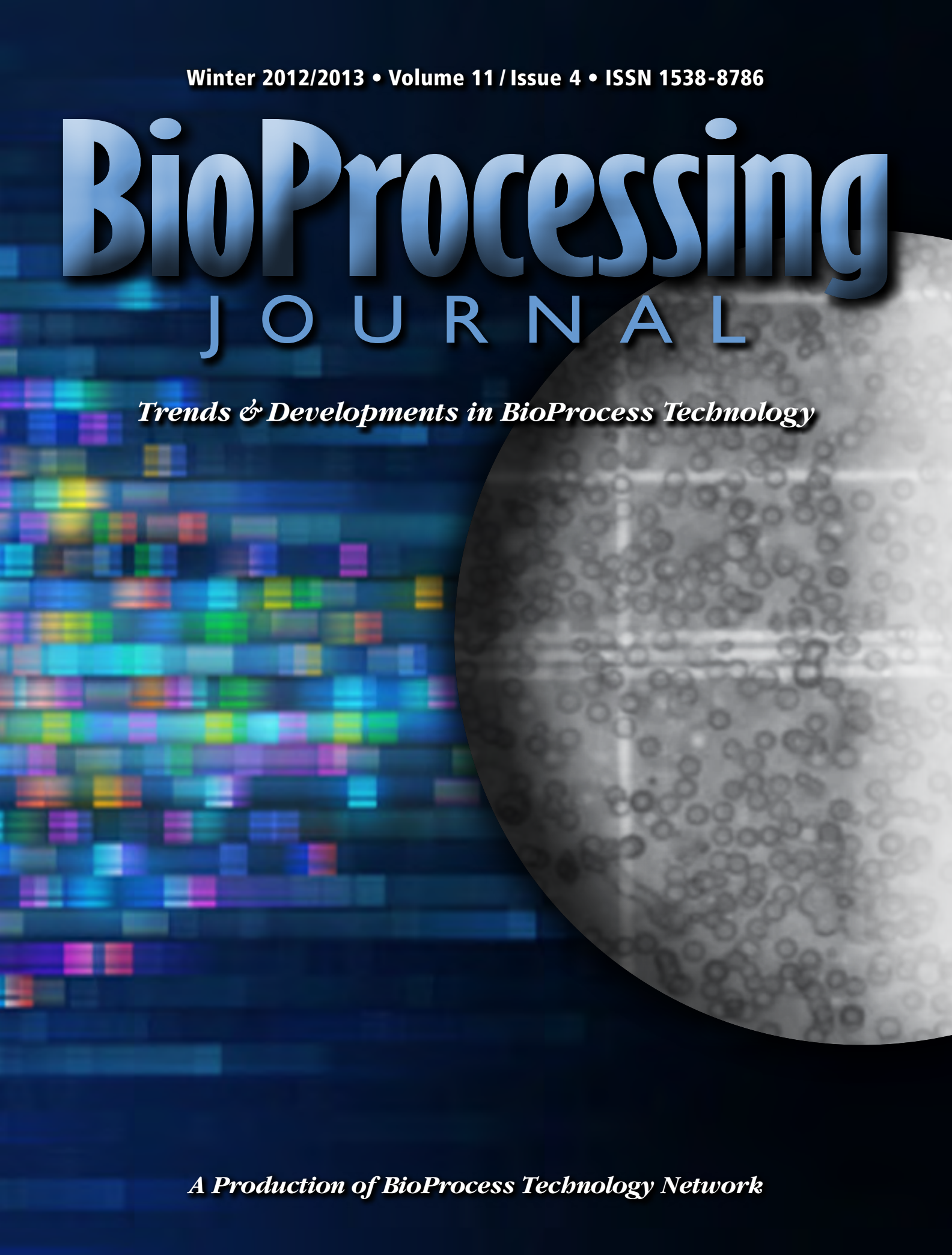

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TRENDS & DEVELOPMENTS IN BIOPROCESS TECHNOLOGY

Induced Patent Infringement Breaks Free from Direct Infringement: *The Implications for Bioprocessing*

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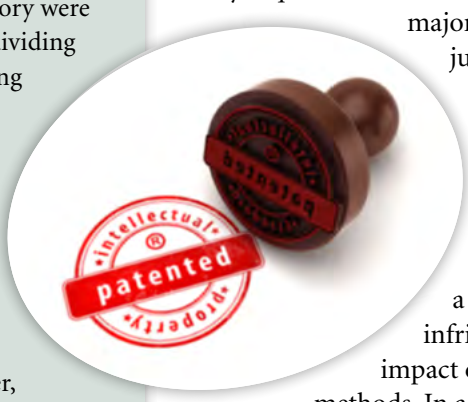
Introduction

Infringement is the unauthorized copying of patented subject matter. Infringement can be either direct or indirect (*e.g.*, induced or contributory), and the issue becomes complicated when the patented subject matter relates to methods. To illustrate, consider the fictional J.P. Jones, PhD, who has developed a burgeoning business in the bioinformatics field by dividing the practice of patented methods amongst several actors. Dr. Jones encouraged medical practitioners to augment their diagnostic resources by utilizing his for-profit laboratory to perform specific DNA analyses. The diagnostic methods collectively being followed by the clinicians and the independent laboratory were patented by another company, but in dividing performance of the method steps among the clinicians and the lab, Dr. Jones was able to ignore the patent rights by exploiting what has often been perceived as a loophole in US patent law. Under these circumstances, the patented protocols were not directly infringed. Consequently, Dr. Jones could not be held liable for inducing patent infringement. However, a September 2012 Appellate Court decision has changed things for Dr. Jones and his contract research organization (CRO).

Changes in Infringement Policy

Issuing a combined decision in *Akamai Technologies, Inc. v. Limelight Networks, Inc.*[1], the Court of Appeals for the Federal Circuit (CAFC) closed loopholes in US patent law by holding that an entity can be held liable for inducing infringement without a finding that any entity was liable for direct infringement.

The *Akamai* decision consolidated the judgments from two cases: *Akamai Technologies, Inc. v. Limelight Networks, Inc.* and *McKesson Technologies, Inc. v. Epic Systems Corp.* The issue in both cases was whether a defendant could be held liable for induced infringement when no single actor performs all the steps of a patented method. Further details about these two cases will be described later in this paper. A deeply divided court declined to follow its prior decisions that an entity can be held liable and distinguished a Supreme Court decision eliminating the single-entity requirement for finding induced infringement. A slight majority, consisting of six of the eleven judges, held that "*...all the steps of a claimed method must be performed in order to find induced infringement, but that it is not necessary to prove that all the steps were committed by a single entity.*"[2] In rejecting the single-entity requirement, the court signaled a dramatic shift in the law of induced infringement. This may have a significant impact on the value of patented bioprocessing methods. In addition to these landmark judgments, two extensive dissents were filed by the five judges who were in the minority on the decision to eliminate the single-entity requirement for finding induced infringement.



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Direct and Induced Infringement of Patented Methods

The law governing patent infringement is provided in Section 271 of Title 35 of the US Code. Subsection 271(b) defines induced infringement:

- *§ 271(b) Whoever actively induces infringement of a patent shall be liable as an infringer.*

Historically, § 271(b) was interpreted as incorporating the requirements of § 271(a), which is often referred to as the "direct infringement" provision:

- *§ 271(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent.*

Liability for direct infringement under § 271(a) requires that a single entity, or a party acting under the entity's direction and control, must commit all the acts necessary to infringe a patent, either personally or vicariously. Direct infringement is a strict liability offense, meaning that knowledge of the infringed patent and intent to infringe are irrelevant— if one performs the proscribed acts, he or she infringes. Were it not for the single-entity rule, parties unaware of a patent and not intending to infringe on it could be brought to court on a charge that they performed a subset of the acts necessary for infringement and were part of a collective effort to directly infringe a patent.

For inventions that are tangible and discrete, such as with products rather than processes, the single-entity rule is upheld and the *Akamai* decision has not disturbed this aspect of the law. A party that manufactures a patented product is a direct infringer under § 271(a) regardless of whether other "upstream" entities contributed to the product. When a single entity is a direct infringer of a patented product, the single-entity rule poses no impediment to finding induced infringement where an inducer does exist. As an example, suppose J.P. Jones' in-house laboratory is going through large amounts of a patented 96-well polycarbonate plate with louvered polypropylene cover and he encourages Acme Plastics to produce them according to the patent specs while subcontracting Smith Assemblers to attach the covers to the plates. Smith is a direct infringer, regardless of its knowledge or intent, and Dr. Jones is an inducer for knowingly encouraging Smith Assemblers to produce the patented 96-well covered microplates.

The legal situation is not as straightforward with patented processes. To prove direct infringement of a patented method, a single entity— an accused infringer or someone acting under its direction or control (*i.e.*, an "agent") — must be found guilty of performing every step of the claimed method. If no single entity can be charged with performing all of the necessary steps, there is no direct infringement. Returning to the scenario described in the introduction, one is able to focus specifically on J.P. Jones's efforts in the field of bioinformatics. Aware of a patented PCR method to precisely determine the amount of nucleic acid in a biological sample, Dr. Jones encouraged research clinicians to obtain patient samples and subsequently encouraged Biome Research to subject those samples to analysis by following the steps of a patented method. Under these circumstances, there is no single entity directly infringing the patented method, and without a direct infringer, the CAFC's 2007 decision in *BMC Resources, Inc. v. Paymentech, L.P.*[3], taught that there could be no inducer of infringement.

Historically, the infringement being induced under § 271(b) was interpreted by looking to the definition of "infringement" provided in § 271(a). Viewed in this light, induced infringement was understood to require: (1) knowledge of the patent and active inducement of infringement; and (2) direct infringement of the patent under § 271(a).

In the *BMC* case, the CAFC relied on the single-entity rule for induced infringement, holding that *"[i] indirect infringement requires, as a predicate, a finding that some party amongst the accused actors has committed the entire act of direct infringement."*[4]

Unlike direct infringement, inducement is not a strict liability offense—instead it requires that the accused infringer knowingly induces infringement and intends to encourage another's infringement.[5] The party that is induced to perform infringing acts does not need to be an agent of the accused infringer for an illegal act to occur. Prior to *Akamai*, therefore, a finding of induced infringement required that the defendant induce a single entity to perform all the steps necessary for infringement.

The Majority Opinion in the Akamai Decisions

In the *Akamai* rulings, the CAFC considered whether induced infringement could be found in situations where a defendant: (a) performs some of the steps of a claimed method and induces other parties to perform the remaining steps, as in the *Akamai* case; or (b) induces other parties to collectively perform all the steps of a claimed method with no single party performing all the necessary steps, as in the *McKesson* case. The lower courts held that the accused infringers, Limelight and Epic respectively, were not liable for induced patent infringement because no single entity had performed all the steps of the claimed methods. The CAFC reversed these judgments and sent the cases back to the lower courts to consider the issue of induced infringement, holding that

liability for induced infringement can be found even if no single party would be liable for direct infringement.[6]

The facts of *Akamai Technologies, Inc. v. Limelight Networks, Inc.* showed that Akamai owned US Patent No. 6,108,703 for a particular method of delivering information from internet websites. In the patented system, webpages were stored on Akamai's servers and modified with Akamai's "tags" before being delivered to users. Limelight provided a similar system for delivering website content, but instead of modifying the webpages itself, Limelight instructed its customers to perform the "tagging" step.

In *McKesson Technologies, Inc. v. Epic Systems Corp.,* US Patent No. 6,757,898 (owned by McKesson) protected a method of electronic communication between a healthcare provider and its patients. Epic licensed the use of a software system in which a patient initiated a communication and the healthcare provider responded. In essence, all the steps of McKesson's patented method were completed, but Epic performed none of the steps itself. The patient and healthcare provider performed the separate steps using the second-party software.

In reaching its decision, the court rejected the interpretation of § 271(b) that *"…unless the accused infringer directs or controls the actions of the party or parties that are performing the claimed steps, the patentee has no remedy, even though the patentee's rights are plainly being violated by the actors' joint conduct."*[7] The interpretation of joint conduct exploited what some perceived as a loophole in infringement law where groups of actors could practice patented methods while avoiding the single-actor requirement for direct and induced infringement. The *Akamai* court decision determined that such a result is *"…wrong as a matter of statutory construction, precedent, and sound patent policy."*[8]

Although the court refined the application of induced infringement to close the loophole in the law, it did so in a manner that did not disturb the requirements for direct infringement under § 271(a). Instead, the court separated the definition of infringement in § 271(b) from the requirements of § 271(a). Following the *Akamai* rulings, finding liability for direct infringement still requires that a single party or its agent commit all the acts necessary for infringement. Turning to induced infringement, however, the court uncoupled directly infringing acts, which are required to find induced infringement, from liability for those acts, which is not required to find induced infringement.[9] Emphasizing the distinction between acts and liability, the court stated that infringement under § 271(b) *"…appears to refer most naturally to the acts necessary to infringe a patent, not to whether those acts are performed by one entity or several."*[10] The court explained that § 271(a) and § 271(b) separately describe conduct that qualifies as infringement but that nothing in the text of § 271 suggests that the act of infringement required for inducement under § 271(b) must qualify as an act that would make a person liable as an infringer under § 271(a) or be limited to infringement by a single entity.[11] Thus, one entity inducing a group of actors to perform a patented method can now be liable for induced infringement because the group performed infringing acts, even though no individual member of that group would be liable as a direct infringer since the acts were divided among the group.

In reaching its decision, the court expressly overruled *BMC* which held that, in order for a party to be liable for induced infringement, some other single entity must be liable for direct infringement.[12] The court also distinguished the *Akamai* case from the *Aro Mfg. Co., Inc. v. Convertible Top Co.* case that was decided by the US Supreme Court.[13] *Aro* recognized that another indirect form of infringement named "contributory" infringement, like induced infringement, requires direct infringement under § 271(a).[14] The CAFC explained that the *Aro* ruling only involved product claims and not divided infringement such as multi-party infringements in the context of method claims.[15] The court noted that, for all the cases addressing induced infringement before *BMC*, *"…in none of those cases did the court hold that, as a predicate for a finding of indirect infringement, all the steps of a method claim must be performed by the same entity."*[16]

In the majority's view, requiring a single entity to directly infringe as a predicate for finding induced infringement *"…would permit ready evasion of valid method claims with no apparent countervailing benefits."*[17] The court, therefore, interpreted the law of induced infringement such that infringement could be found even if no single party was liable for direct infringement. In other words, induced infringement occurs in the event that no single party completes all the steps of the patented method, yet the accused infringer has induced (knowingly caused, urged, encouraged, or aided) the performance of all the steps of the method and those steps are subsequently performed.[18]

The Dissenting Opinions in the Akamai Case

The five dissenting judges of the full court filed two lengthy and sharply worded criticisms of the majority opinion. Circuit Court Judge Richard Linn spoke on behalf of four judges in support of maintaining the single-entity rule for acts of direct infringement, supporting a charge of induced infringement, and Judge Newman filed her own dissenting opinion arguing that the single-entity rule should be abolished in all contexts.

The Linn dissent criticized the majority for rewriting § 271(a) and § 271(b) and going against the controlling statute and long-standing Supreme Court precedent.[19] The dissent described the majority decision as "*…an abdication of this court's obligation to interpret Congressional policy rather than alter it.*"[20] The dissent faulted the majority's refusal to interpret § 271(a) and its willingness to separate § 271(b) from § 271(a), arguing that the majority effectively and impermissibly rewrote § 271(b) to read " '*...[w]hoever actively induces infringement of [or induces two or more separate parties to take actions that, had they been performed by one person, would infringe] a patent shall be liable as an infringer.*' "[21] The Linn dissent asserted that "*…the plain language of the statute and the unambiguous holdings of the Supreme Court militate for adoption…of the prior decisions of the court…which hold that liability under § 271(b) requires the existence of an act of direct infringement under § 271(a), meaning that all steps of a claimed method be practiced, alone or vicariously, by a single entity or joint enterprise.*"[22]

The dissent agreed with the court's rulings in *BMC* and *Muniauction*[23], supporting a single-entity rule in induced infringement. *Muniauction* quoted *BMC's* characterization of the single-entity rule as "*...the proper standard for whether a method claim is directly infringed by the combined actions of multiple parties.*"[24] *Muniauction* upheld the single-entity rule, stating that "*...where the actions of multiple parties combine to perform every step of a claimed method, the claim is directly infringed only if one part exercises 'control or direction' over the entire process such that every step is attributable to the controlling party, i.e., 'the mastermind.'* "[25] The Linn dissent also dismissed the majority's distinction of *Aro* and instead cited this particular case as evidence that the US Supreme Court expressly rejected separating indirect infringement from direct infringement.[26] In addition to liability for a single entity, the dissent noted that the actions of a joint enterprise, requiring multiple parties linked by an agreement, shared purpose, and common economic interest, would establish liability for induced infringement.[27]

The Linn dissent concluded that, contrary to the majority's decision, "*…direct infringement is required to support infringement under § 271(b)…and properly exists only where one party performs each and every [step of the patented method] or is vicariously liable for the acts of others in completing any steps of a method claim, such as when one party directs or controls another in a principal-agent relationship or like contractual relationship, or participates in a joint enterprise to practice each and every limitation of the claim.*"[28] The Linn dissenters would have affirmed the lower courts' findings of non-infringement by Limelight and Epic.

In a separate opinion, Judge Newman disagreed with both the majority and the other dissenting judges, characterizing the rules for induced infringement offered by both sides as "*…two flawed positions, each a departure from established precedent, each poorly suited to the issues and technologies that dominate today's commerce.*"[29] She described the majority decision as creating an "*inducement-only rule*" where merely advising or encouraging infringing acts can qualify as direct infringement and only the inducer, but not the direct infringers, is liable. According to her dissent, such a rule "*…is not in accordance with statute, precedent, and sound policy…and contains vast potential for abuse.*"[30]

Judge Newman broke from the other dissenting judges in urging repudiation of the single-entity rule for direct and induced infringement. She argued that the "*whoever*" in § 271(a) should be understood as encompassing both single and multiple entities because "*…[i]nfringement is not a question of how many people it takes to perform a patented method.*"[31] Under her interpretation, both direct and induced infringement could be defined "*…as occurring when all of the claimed steps are performed, whether by a single entity or in interaction or collaboration.*"[32]

Implications for the BioProcess Community

The decision of the CAFC in the *Akamai* rulings may have a significant impact on patented methods for specific bioprocess applications including assay methods, cell line development and reproduction, as well as processes for developing and producing biological products such as biosimilars. The rejection of the single-entity rule for induced infringement could make patent claims for bioprocessing methods easier to draft and enforce. Before *Akamai*, patent claims were ideally drafted to avoid situations of divided or multi-party infringement. The court remarked in *BMC* that "*...concerns over a party avoiding infringement by arms-length cooperation can usually be offset by proper claim drafting. A patentee can usually structure a claim to capture infringement by a single party.*"[33] Some bioprocesses, however, such as methods that include steps of administering a diagnostic reagent and processing biological samples often involve acts performed by different entities such as treating physicians and independent clinical laboratories. In the absence of the requirement that a single party perform all the steps of a patented method, patents for these methods may increase in value due to the ease in establishing liability for induced infringement. As Judge Newman noted in her dissent, however, the majority decision creates uncertainties in the level of inducement necessary for finding infringement liability and in the remedies available for induced infringement where no direct infringers exist.[34]

Another potential consequence of *Akamai* is the removal of territorial limits on infringing activity. The text of § 271(a) requires that all infringing acts be committed in the United States to establish liability. When § 271(b) was read to include the requirements of § 271(a), induced infringement contained the same territorial constraints. As Law Professor Timothy Holbrook has remarked, *"…[b]y removing § 271(a) as a prerequisite to induced infringement, it seems that the strict territorial rule should also be removed. Conceivably, one could induce infringement of a method claim when performance of the method straddles territorial borders."*[35] Following *Akamai*, therefore, the question remains about how extra-territoriality will be treated in the context of induced infringement.

Conclusion

The recent CAFC decision to overrule the single-entity requirement for induced infringement liability in *Akamai* has surprised many in the patent bar as well as those in affected industries. The full impact of the decision on patented methods remains unclear, however, because the deep divisions within the CAFC lead many to expect that the US Supreme Court or even a Congressional Act will be needed to clarify the standard for induced infringement.

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[4] *BMC*, 498 F.3d at 1379.
[5] *Akamai*, 692 F.3d at 1308.
[6] *Akamai*, 692 F.3d at 1319.
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[10] *Akamai*, 692 F.3d at 1309.
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[12] *Akamai*, 692 F.3d at 1306.
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[14] *Aro*, 365 US at 341.
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