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A First Look at the Abbreviated Follow-on Biologic Regulatory Pathway

As the biologic drug industry continues to develop innovative therapies, consumer costs rise concomitantly. Most biologic drugs are at present regulated by the Food & Drug Administration (FDA) under § 351 of the Public Health Services Act (PHSA),¹ and are not subject to the provisions of the Hatch-Waxman Act² that promote generic versions of small molecule drugs. Thus, innovator biologic companies have been free of generic competition, primarily due to substantial cost barriers that prevented biogenerics from entering the market. As a result, these innovator companies have been able to recoup their high development costs, making them attractive to investors. Congress has attempted to pass legislation to establish a “biogeneric” (also called “follow-on biologics”

or “biosimilars”) drug regulatory approval pathway for several years, including several bills introduced in 2009. These bills aimed to provide a regulatory pathway that balanced the promotion of generic competition for biologics and reduced consumer treatment costs, while simultaneously maintaining incentives for innovators to discover new market-viable biologic medicines.

On March 21, 2010, the House of Representatives voted in favor of the Senate version of the *Patient Protection and Affordable Care Act* (H.R. 3590)³ by a narrow 219-212 margin. This health care reform bill has generated enormous media coverage, yet Title VII of the bill containing the *Biologics Price Competition and Innovation Act* *continued on p. 2*

The After Effects of *In Re Bose*

Increasingly, parties have alleged fraud when challenging the validity of their competitors’ trademark registrations. Often, the allegations of fraud arise from what may seem like good faith mistakes during the application for, or renewal of, a trademark registration. These mistakes frequently involve the mis-identification of the goods and services with which a mark is used. Parties often support such allegations of fraud by citing recent decisions from the U.S. Patent and Trademark Office (“Trademark Office”).

The Trademark Trial and Appeal Board’s (“TTAB”) decision in *Medinol Ltd. v. Neuro Vasx, Inc.*¹ appeared to lower the standard by which fraud on the Trademark Office is assessed. Recently, the Federal Circuit clarified the fraud standard in *In re Bose Corp.*,² thereby potentially curtailing the number of cancellation proceedings filed with the TTAB. *In re Bose* overruled *Medinol*³ and

expounded on the holding from *Torres v. Cantine Rorresella S.r.l.*,^{4,5} the case on which *Medinol*’s reasoning rested.

This article discusses the recent history of the fraud standard in the Trademark Office in view of these three cases, reviews the TTAB’s subsequent application of the *In re Bose* holding, and concludes with practice tips to avoid the inadvertent commission of fraud.⁶

Torres – You Should Have Known

The Federal Circuit stated that “[f]raud in procuring a trademark registration or renewal occurs when an applicant knowingly makes false, material representations of fact in connection with his application.”⁷ The elements, then, for committing fraud against the Trademark Office are: (1) a knowing intent to deceive; and (2) a *continued on p. 5*

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of 2009 has escaped much scrutiny. This section of the bill creates a regulatory framework for the approval of biogeneric or follow-on biologic (FOB) drugs.⁴ Since none of the pending H.R. 3590 amendments affect this subsection, it appears that the regulatory framework for FOBs is now in place. This article provides an initial examination of the text of the bill, with a focus on FOB licensing pathway procedures, and particularly the key issues of data exclusivity and interchangeability.

Patent Information Exchange Timeline

Similar to the abbreviated pharmaceutical drug approval pathway of the Hatch-Waxman Act, patents are closely integrated within the FOB licensing pathway. However, rather than an “Orange Book” equivalent for biologic drugs, H.R. 3590 creates a patent information exchange regime between the FOB applicant and the reference product sponsor (i.e., the biologics innovator). This exchange occurs over a restricted time frame, and emphasizes communication between the FOB applicant and the reference product sponsor prior to the filing of any infringement suit.

The timeline begins when the FDA notifies the FOB applicant that its application has been accepted for review. From that date, the FOB applicant has 20 days to provide the reference product sponsor with the FOB application and “such other information that describes the process or processes used to manufacture the biological product.”

Upon receipt of this information from the FOB applicant, the reference product sponsor has 60 days to provide to the FOB applicant “a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted” if the FOB was put on the market, as well as identification of which (if any) of those patents the sponsor would be willing to license to the FOB applicant.

After receiving this patent list, the FOB applicant has 60 days to submit to the reference product sponsor “a detailed statement that describes, on a claim-by-claim basis, the factual and legal basis of the opinion of the [FOB] applicant that such patent is invalid, unenforceable, or will not be infringed” by commercial marketing of the FOB product. Alternatively, the FOB applicant can submit a statement that it does not intend to begin commercial marketing of the FOB product prior to expiration of the identified patent(s).



The text of H.R. 3590 reveals some practical considerations for both innovator biologic drug companies and potential FOB applicants to be as ready as possible for their initial experience with the framework for regulatory approval of follow-on biologics.

Finally, the reference product sponsor then has 60 days to provide the FOB applicant with a detailed statement that describes on “a claim-by-claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product” and respond to the FOB applicant’s statement concerning validity and/or enforceability.

The bill then mandates a 15 day period for negotiation between the reference product sponsor and the FOB applicant to determine which patent(s) will be the subject of an action for patent infringement. At the

conclusion of the negotiation, the reference product sponsor has 30 days to bring an infringement suit against the FOB applicant. Whether or not the reference product sponsor brings an infringement suit has a direct impact on the exclusivity granted to the first approved FOB applicant.

Data Exclusivity for Reference Product and First Interchangeable Biological Product

One of the features of generic approval pathways (for both traditional drugs and biologics) is that the generic drug applicant is permitted to use the innovator’s data for safety and efficacy of the drug after expiration of a “data exclusivity” period. Leading up to the passage of H.R. 3590, innovator biologic companies argued that data exclusivity was particularly important in order to attract investment and further encourage innovation. Biotechnology companies generally spend significantly more on research and development than do their traditional chemical drug counterparts, since the development of biologics is highly complex and involves greater resources for drug production.⁵

During the period of data exclusivity, the FDA will not permit the generic biological drug maker to use any of the innovator company’s data regarding the approved biologic in support of the generic company’s effort to acquire a FOB license. This effectively halts any abbreviated licensure of a FOB prior to the expiration of the data exclusivity period, because the FOB applicant would have to generate and submit its own full report of safety and efficacy data.⁶ To date, the cost of producing this data has effectively inhibited biogeneric drug makers from entering the market to compete with the innovator biologic.

This period of data exclusivity is separate and distinct from any right to exclude based

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on patents, and these time periods would run concurrently. Prior to the passage of H.R. 3590, innovators enjoyed an infinite data exclusivity period. H.R. 3590 provides 12 years of data exclusivity for the reference product.⁷ This portion of the bill precludes a FOB application from being approved “until the date that is 12 years after the date on which the reference product was first licensed.” The bill also offers an additional 6 months of data exclusivity for the use of biologics “in the pediatric population” or approved for a “rare disease or condition.”⁸ Further, no FOB applications will be reviewed by the FDA until 4 years after the date the reference product was first licensed. The bill provides limited flexibility to the reference product sponsor to supplement or modify the approved reference product. Consumer groups, such as those groups that consider patient access and reducing treatment costs as more pressing policy issues than promoting innovation, had argued for a shorter data exclusivity period, which would hasten the availability of FOBs and promote competition; these provisions were not enacted in the final bill.⁹

Reminiscent of the 180 days of market exclusivity granted to the first filed abbreviated new drug application (ANDA) under the Hatch-Waxman Act,¹⁰ H.R. 3590 encourages generic FOB development by providing a period of market exclusivity for the first approved interchangeable FOB.¹¹ The first approved interchangeable FOB applicant is granted a period of market exclusivity which depends on the status of the patent litigation with the innovator biologic. If the reference product sponsor chooses not to bring suit against the FOB applicant, the FOB applicant receives 18 months of post-approval market exclusivity. If the reference product sponsor brings suit against the FOB applicant, the FOB applicant receives a market exclusivity term of 42 months from the date of approval or 18 months after the final court decision,

whichever ends first.

Biosimilarity and Interchangeability Standards

There are several scientific challenges presented by an abbreviated FOB regulatory pathway, not the least of which is the difficulty in measuring the differences (especially structural differences), and their effects, between the reference product and the FOB. Due to this difficulty, legislators have struggled to determine the standard for how “biosimilar” the reference product and the FOB must be, and whether FOB drugs must be “interchangeable” with the reference product.

Biologic drugs are typically large, heterogeneous protein molecules derived from living cells and manufactured in recombinant cells expressing exogenous DNA, while conventional drugs are typically small molecules produced using predictable chemical synthesis. Unlike small molecules, which can be produced as exact copies of the innovator drug, slight changes in the manufacturing process for biologic drugs can alter the complex structure of the biologic drug itself, which can result in subtle, hard-to-detect structural differences between the reference product and the FOB. Even these small differences can result in significant adverse effects, such as decreased half-life or uptake of the drug, altered patterns of biological distribution in different tissues, and immunological reactivity. The likelihood (and severity) of these adverse effects are expected to increase as the number of differences increase.

For a biologic drug to be considered “interchangeable” under H.R. 3590, it must be capable of being “substituted for the reference product without the intervention of the health care provider who prescribed the reference product.”¹² To be deemed safe for interchangeability, the FOB must be

both “biosimilar to the reference product” and “expected to produce the same clinical result as the reference product.”¹³ There must be no increased safety or efficacy risk by switching between use of the FOB product and the reference product, and the FOB applicant must demonstrate that “the biological product and reference product utilize the same mechanism or mechanisms of action.”¹⁴ The FOB applicant must establish that the FOB has the same route of administration and dosage as the reference product, and the manufacturing process and facility of the FOB must be approved.

Most importantly, H.R. 3590 requires the FOB applicant to provide data that establishes biosimilarity to the reference product. This data can take the form of (1) analytical studies that demonstrate that the active biological in the FOB product is “highly similar” to the reference product, (2) animal studies, and (3) clinical studies that are sufficient to demonstrate the safety, purity, and potency of the FOB use (including immunogenicity).¹⁵ Under certain circumstances, these requirements may be waived at the discretion of the FDA.¹⁶

The biosimilarity standards provided in H.R. 3590 are purposefully imprecise and are intended to be flexible, as advances in biotechnology will necessitate such flexibility. Indeed, under H.R. 3590, the FDA reserves the right to supply general or specific guidance over the standards for licensure of a biological product. This guidance includes “criteria that the [FDA] will use to determine whether a biological product is highly similar to a reference product,” or guidance based on “science and experience,” that prevents approval of FOBs in a certain product class.¹⁷ If the FDA chooses to issue such guidance, H.R. 3590 requires the FDA to provide the public with an opportunity to comment

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on any such guidance.¹⁸ This should provide an opportunity for both innovator and biogeneric companies to contribute to how the FDA develops guidelines for interchangeability and biosimilarity.

Practical Considerations

As with any new legislation, the full impact of the *Biologics Price Competition and Innovation Act* will become clear only over time. For now, biotechnology companies and their counsel are left to speculate on how the legislation will ultimately function in practice. Nonetheless, the text of H.R. 3590 reveals some practical considerations for both innovator biologic drug companies and potential FOB applicants to be as ready as possible for their initial experience with the new framework.

First, due to the strict timeframe of patent information exchange leading up to infringement litigation, reference product companies should evaluate the strengths and weaknesses of their patents now so that they will be able to quickly select the best patents to assert against FOB applicants. Similarly, potential FOB applicants should be aware of which patents may be raised against their FOB application and prepare their statements of invalidity, non-infringement, and unenforceability of these relevant patents.

Second, both innovators and FOB applicants should maximize their exclusivity period. Innovator biologics should evaluate whether pediatric studies are appropriate or whether the reference product treats a “rare disease or condition” in order to acquire an additional 6 months of data exclusivity. FOB applicants, after generating the required biosimilarity data, should strive to be the first to apply for a FOB license to capture the market exclusivity provided to the first interchangeable product.

Finally, all biotechnology companies should

be prepared to contribute to the FDA guidelines for biosimilarity. The bill requires the FDA to invite public comment on licensing guidelines, and companies should actively provide such comments to aid the FDA in their biosimilarity determinations. Companies should begin formulating their positions as the FDA guidelines could have a direct effect on future biologic licenses. Indeed, the FDA should carefully consider any information submitted by the reference drug sponsor prior to issuing any guidance for the approval of a FOB application, as the reference product sponsor will have the most experience with the approved biologic.

Endnotes

1. Public Health Services Act § 351, 42 U.S.C. § 262 (2006).
2. The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98-417 (1984), 21 U.S.C. §§ 355, 357.
3. H.R. 3590, 111th Cong. (2009), available at thomas.gov.
4. *Id.* at § 7002.
5. See, e.g., Donald L. Zuhn, *Amgen VP Makes Case for Longer Exclusivity Period in Follow-on Biologics Legislation*, Patent Docs weblog, April 22, 2009, <http://www.patentdocs.org/2009/04/amgen-vp-makes-case-for-longer-exclusivity-period-in-follow-on-biologics-legislation.html>; Donald L. Zuhn, *BIO CEO Makes Case for 12-Year Data Exclusivity Period*, Patent Docs weblog, Aug. 16, 2009, <http://www.patentdocs.org/2009/08/bio-ceo-makes-case-for-12-year-data-exclusivity-period.html>.
6. In at least one instance, a biogenics manufacturer performed bioequivalency testing necessary to obtain FDA approval without relying on the innovator's data. See Kevin E. Noonan, *Insmad Announces Bioequivalent G-CSF Biologic*, Patent Docs weblog, July 10, 2008, <http://www.patentdocs.org/2008/07/insmed-announce.html>.
7. H.R. 3590, 111th Cong. § 7002 (2009).
8. *Id.*
9. Generally, the term proposed by these groups paralleled the 3.5 to 5 years contained in the Hatch-Waxman Act. Groups in support of a shorter data exclusivity period include the Federal Trade Commission, National Coalition on Health Care, AARP, and the Office of Management and Budget.
10. 21 U.S.C. § 355(j) (2006).

11. *Id.*
12. H.R. 3590, 111th Cong. § 7002 (2009).
13. *Id.*
14. *Id.*
15. *Id.*
16. This discretion, if not administered judiciously, could be a significant source of potentially harmful exercise of agency discretion.
17. *Id.*
18. *Id.*

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false material representation.⁸ The focus of recent case law involves the standard by which the “intent to deceive” element is measured.

In *Torres*, the Federal Circuit affirmed a TTAB decision canceling *Torres*’ registration due to fraud.⁹ *Torres* obtained a registration for the trademark “LAS TORRES” below a design depicting castle-like towers for wine, vermouth, and champagne. In a renewal declaration, *Torres* stated that the mark was still in use in interstate commerce for the foregoing products and attached a specimen of the mark as registered. *Torres* was not, however, using the registered mark at the time he filed the renewal declaration. Instead, he was using the name “*Torres*” (no “*Las*”) with an altered design on only wine, not on vermouth or champagne. *Torres* filed an affidavit explaining that he did not consider the alteration material. The TTAB disagreed and granted summary judgment canceling the registration due to fraud.

The Federal Circuit affirmed based on the fact that *Torres* was no longer using the registered trademark in commerce or with the goods stated in the original registration.¹⁰ The court stated that “[t]he problem of fraud arises because *Torres* submitted a label that he *knew or should have known* was not in use that contained a mark clearly different from the one in use.”¹¹ These statements by the Federal Circuit led the TTAB to rest its holding in the later *Medinol* case on the “*knew or should have known*” language from *Torres*.

Medinol – Make No Mistakes

In *Medinol*, registrant Neuro Vasx, Inc. applied for the trademark NEUROVASX, stating its intent to use the mark for stents and catheters.¹² Subsequently, when a Notice of Allowance issued for the mark, Neuro Vasx filed a statement of use

confirming that the goods/service identified in the Notice of Allowance were the same goods/services with which it was using its mark in commerce.¹³ *Medinol* brought a petition to cancel the NEUROVASX registration, pleading that Neuro Vasx had never used the mark on stents and that it knowingly provided false and fraudulent statements to the Trademark Office during prosecution of the mark.¹⁴ Neuro Vasx responded by admitting that it made an error to include stents as one of the goods connected with the mark.¹⁵

The logo for snippets, featuring the word "snippets" in a red, lowercase, sans-serif font. The letter "i" has a red square dot, and the letter "p" has a red square stem.

Although the legal landscape regarding fraud against the Trademark Office may seem more forgiving since *In re Bose*, applicants must remain diligent.

The TTAB acknowledged the error, but still found that Neuro Vasx’s intent in submitting the incorrect statements was fraudulent.¹⁶ Further, the TTAB stated that “[t]he appropriate inquiry is therefore not into the registrant’s subjective intent, but rather into the objective manifestations of that intent.”¹⁷ Consequently, the “undisputed facts in this case clearly establish that respondent [Neuro Vasx] *knew or should have known* at the time it submitted its statement of use that the mark was not in use on all of the goods.”¹⁸ Although the TTAB did not cite *Torres*, it stated that the fact that the false statements were made in error does not belie the fact that the registrant “*knew or should have known*”¹⁹ that its statements were incorrect. “[A]ll that is required to establish intent to commit fraud” was

registrant’s knowledge that the mark was not used on stents.²⁰ The TTAB granted a summary judgment motion for fraud based on this reasoning²¹ and, thus, the *Medinol* decision appeared to move the standard for proving “intent to deceive” closer to a negligence standard.

In re Bose Brings Wave of Clarity

In *In re Bose*, Hexawave filed a claim to cancel Bose’s WAVE mark due to fraud.²² Hexawave pleaded that in Bose’s application for renewal of the registration, Bose’s general counsel indicated that the mark was still used in commerce with respect to audio tape recorders and players.²³ The mark, however, was not used in association with any new audio tape recorders or players.²⁴ Bose’s general counsel was aware of this fact, but still indicated that the mark was used on such goods because Bose still repaired these types of goods, and, thus, he believed the mark was still used in commerce with those goods.²⁵ The TTAB found Bose’s general counsel’s belief to be unreasonable and hence found Bose to have committed fraud against the Trademark Office based on the false statements on its renewal application—despite no apparent intent to deceive.²⁶

On appeal, the Federal Circuit disagreed and found that Bose did not commit fraud, holding that there “is no fraud if a false misrepresentation is occasioned by an honest misunderstanding or inadvertence without a willful intent to deceive.”²⁷ The Court overruled *Medinol*, stating that although “intent must often be inferred from the circumstances,” by “equating ‘*should have known*’ of the falsity with a subjective intent, the Board erroneously lowered the fraud standard to a simple negligence standard.”²⁸ The Federal Circuit’s decision in *In re Bose* thus changed the legal

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landscape for trademark registration cancellations due to fraud.

The Landscape After *In re Bose*

The TTAB recently had occasion to apply the holding of *In re Bose* in *Enbridge, Inc. v. Excelebrate Energy Limited Partnership*,²⁹ and found no fraud during opposition proceedings for the mark ENERGYBRIDGE.³⁰ In *Enbridge*, the applicant inadvertently listed “transmission of oil” as one of the services applied for during prosecution.³¹ The TTAB denied Excelebrate’s motion for summary judgment on its fraud claim, holding that the “record does not support the conclusion that there is no genuine issue that applicant had the requisite intent to deceive when it asserted use of its mark in connection with the services.”³² Thus, the TTAB appeared to follow the *In re Bose* requirement of a willful intent to deceive to support a finding of fraud.

Ramifications and Practice Tips in Light of *In re Bose*

Since *In re Bose*, the number of opposition and cancellation proceedings based on fraud has significantly decreased. In the six months before *In re Bose*, the authors identified fourteen cases filed with the TTAB where at least one claim dealt with fraud. Conversely, in the six months after *In re Bose*, the authors found only one fraud case (*Enbridge*) filed with the TTAB.

Although the legal landscape regarding fraud against the Trademark Office may seem more forgiving since *In re Bose*, applicants must remain diligent. Applicants should work closely with outside counsel and employees to properly identify goods and services during all stages of application and registration. For example, when preparing intent-to-use applications, applicants should identify only those goods and services for which the applicant has a *bona fide* intent

to use its mark. Similarly, when submitting an allegation of use, a statement of use, or a use-based application, applicants should identify only those goods or services with which the applicant is currently using the mark. And, when filing a renewal or declaration of continued use, applicants should delete goods or services with which the mark is not actively being used. Such procedures will help prevent mistakes from being made, and mitigate against a finding of intent to deceive in instances where mistakes nonetheless occur.

Endnotes

1. 67 U.S.P.Q.2d 1205, 2003 WL 21189780 (T.T.A.B. 2003).
2. 580 F.3d 1240 (Fed. Cir. 2009).
3. *Id.* at 1245 (“By equating ‘should have known’ of the falsity with a subjective intent, the Board erroneously lowered the fraud standard to a simple negligence standard.”).
4. 808 F.2d 46 (Fed. Cir. 1986).
5. *In re Bose Corp.*, 580 F.3d at 1245 (“The ‘should know’ language, if it signifies a simple negligence or a gross negligence standard, is not only inconsistent with the framework set out elsewhere in *Torres*, but would also have no precedential force as it would have conflicted with precedents from CCPA.”).
6. *Enbridge, Inc. v. Excelebrate Energy Ltd. P’ship*, 92 U.S.P.Q.2d 1537, 2009 WL 3541047 (T.T.A.B. 2009).
7. *Torres*, 808 F.2d at 48. See also *In re Bose*, 580 F.3d at 1243.
8. *Torres*, 808 F.2d at 48. (“[T]he obligation which the Lanham Act imposes on an applicant is that he will not make knowingly inaccurate or knowingly misleading statements . . .”) (citing *Bart Schwartz Int’l Textiles, Ltd. v. FTC*, 289 F.2d 665, 669 (CCPA 1961)) (emphasis in original).
9. *Id.* at 47.
10. *Id.* at 48 (“Clearly, under the circumstances, *Torres* knew or should have known that the mark as registered and the specimen submitted were not currently in use when he filed his renewal application.”).
11. *Id.* at 49 (emphasis added).
12. 2003 WL 21189780 at *1.
13. *Id.*
14. *Id.* at *2.
15. *Id.* (“At the time the Statement of Use was prepared, the fact that the goods identified in the

Notice of Allowance also included ‘stents,’ in addition to catheters, was apparently overlooked.”).

16. *Id.* at *6. (“Respondent’s [Neuro Vasx] explanation of the misstatement (which we accept as true) – that the inclusion of stents in the notice of allowance was ‘apparently overlooked’ – does nothing to undercut the conclusion that respondent knew or should have known that its statement of use was materially incorrect.”).
17. *Id.* at *5.
18. *Id.* at *6 (emphasis added).
19. *Id.*
20. *Id.*
21. *Id.*
22. 580 F.3d at 1242.
23. *Id.*
24. *Id.*
25. *Id.*
26. *Id.* at 1242-43.
27. *Id.* at 1246.
28. *Id.* at 1244 (emphasis added).
29. 2009 WL 3541047 at *1.
30. *Id.*
31. *Id.* at *2.
32. *Id.* at *6.

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The *Qui Tam* Patent False Marking Statute: An Open or Shut Case?

Introduction

Falsely marking a patent number (or patent pending) on an article is a statutory offense, and is governed by § 292 of the Patent Act.¹ This statute is certainly not new,² and has not stirred up much interest or provoked many false marking lawsuits—until recently.

In 2007, Solo Cup Company was sued for false marking,³ and shortly thereafter, other large entities, such as Brooks Brothers⁴ and Proctor & Gamble,⁵ were also sued. But it was the suit involving two lesser-known companies, Forest Group and Bon Tool Co., that really brought the spotlight to § 292.

In December 2009, the Federal Circuit, in *Forest Group, Inc. v. Bon Tool Co.*,⁶ departed from an interpretation of the false marking statute that had been established for almost one hundred years. Since the 1910 case *London v. Everett H. Dunbar Corp.*,⁷ the “every such offense” language of the statute⁸ was interpreted to mean every decision to falsely mark.⁹ The rationale for this interpretation was to punish the decision to mark, rather than to punish per article manufactured, so as to avoid a damages award that would “accumulate as fast as a printing press or stamping machine might operate.”¹⁰

This interpretation was commonly applied up until the *Forest* decision in December 2009. In that decision, the Federal Circuit significantly raised the stakes for false marking offenders by interpreting the statutory “\$500 for every such offense” to mean that a fine of up to \$500 could be applied on a “per article” basis.¹¹ This new interpretation has provoked the filing of over 100 new lawsuits to date,¹² as there now appears to be a much bigger bounty to be won by a plaintiff.

In the wake of the large wave of recent cases, old case law will be reevaluated, and many new issues will be raised. What are the issues that remain open, and what are the issues that are relatively settled by the courts?

Mechanics of a False Marking Action

Qui tam statutes

Section 292(b) is a *qui tam* provision, which means that “any person” may bring an action for false marking.¹³ *Qui tam* actions provide an incentive for a citizen to bring cases before the court so that the government does not have to spend the time and resources to do so.¹⁴ However, the *qui tam* plaintiff must split any recovery with the federal government.¹⁵

In comparison to other *qui tam* statutes in existence today, § 292 is spartan regarding the mechanics of such an action. For example, the False Claims Act (FCA), another *qui tam* statute, provides a statutory mechanism for a private party bringing an action, dictating how the lawsuit will unfold and the interaction between the government and the party bringing suit.¹⁶

By contrast, Section 292 is silent, however, regarding whether a private party bringing a false marking action is to notify the government of the action or provide the government with a copy of the complaint. Additionally, § 292 provides no statutory mechanism for the government to intervene in the action or to take over the action. Rule 24 of the Federal Rules of Civil Procedure allows an interested party to join in an action, so technically the government could join as a co-plaintiff.¹⁷ However, Rule 24 does not permit the government to take over the action, as the FCA allows.

Who can bring suit?

Section 292(b) states that “any person” can bring a *qui tam* suit. Can a “person” be any entity, or only a natural person? Some early cases held that a corporation was foreclosed from bringing suit for an “informer” case, such as a *qui tam* false marking suit.¹⁸ However, subsequent cases have held otherwise, and it now seems settled that a corporation may bring a *qui tam* false marking suit.¹⁹

Government permission to settle

There is no statutory provision requiring consent of the government to settle an action under § 292. If the government intervenes as a co-plaintiff, then presumably the government would have to agree to any settlement.²⁰ However, if the government does not intervene as a co-plaintiff, presumably the *qui tam* plaintiff may settle the lawsuit without permission of the government.

Multiple actions for the same instances of false marking

Unlike the FCA, there is no statutory provision under § 292 directly preventing multiple plaintiffs from bringing duplicative actions against a patentee for the same instances of false marking. At common law, only the first party to file a *qui tam* action could maintain that action, and the outcome of that action was preclusive on that issue, not only as to all parties including the government, but as to other would-be *qui tam* plaintiffs as well.²¹

As of the Federal Circuit’s decision in *Forest*, however, no district court had been called upon to decide whether two plaintiffs can maintain two separate actions for false marking of the same articles, or whether subsequent plaintiffs can join in the action of the first plaintiff. Since the

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Forest decision, there have been multiple instances of separate lawsuits alleging the same acts of false marking.²² Defendants will likely move to dismiss the later-filed cases, arguing that they would lead to overlapping, inconsistent, and double (or more) damages to be paid. How the courts will resolve this issue remains to be seen.

Collusion

After initiation of an action under § 292, settlements are, of course, possible. A scenario could be envisioned where an entity with potential financial exposure for false marking arranges with a “friendly” to file suit against the entity for false marking, the parties settling soon thereafter for a nominal amount. There may not have been much motivation to arrange such an “under the table” deal before the *Forest* decision, but now that *Forest* has apparently opened the door to potential windfall financial recoveries for whistleblowers, a would-be defendant may be tempted to collude with a potential plaintiff to prevent a future whistleblower from suing over the same falsely marked articles, assuming of course that the above-discussed questions regarding issue preclusion would be resolved in favor of such a defendant.

Early commentators suggest that any decision or settlement of a *qui tam* action that was a result of collusion between a plaintiff and a defendant would render the decision void, allowing a second, subsequent plaintiff to bring suit based on the same wrongdoing alleged in the first action.²³ No court interpreting § 292 has yet had the opportunity to address the question of whether a collusive settlement or action renders the settlement void. However, given the recent torrent of false marking suits, it is conceivable that courts may be asked to address this question.

Standing

As noted, *qui tam* statutes provide persons with the right to bring suit on behalf of the government and to share in any financial recovery.²⁴ How this right fares when confronted by a Constitutional standing challenge, however, is not yet clear.

Some courts have been challenged with whether a “private” plaintiff has “standing” to sue in a *qui tam* suit. In *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, the Supreme Court held that

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In the wake of the large wave of recent false marking cases, old case law will be reevaluated, and many new issues will be raised.

all plaintiffs, including *qui tam* plaintiffs, must satisfy the “irreducible constitutional minimum of standing.”²⁵ In the recent case of *Stauffer v. Brooks Bros.*,²⁶ the district court cited *Vermont Agency* and held that, in the context of a *qui tam* claim for false marking under § 292, standing requires a plaintiff to plead an actual or imminent injury to itself, the Government, or the public, as a result of intentional false marking.²⁷ In *Stauffer*, the court held that there was no injury-in-fact to the government or the public.²⁸

The *Stauffer* court’s decision may have raised the bar for standing by effectively requiring a proprietary injury to the government or the public.²⁹ That decision is seemingly in contrast to the Supreme Court’s decision in *Vermont Agency*, which

expressly recognized that the government may suffer injury simply by a violation of its laws, even if it suffers no proprietary injury.³⁰ Also in contrast to *Stauffer*, the district court in *Pequignot v. Solo Cup Co.*³¹ recognized that the only injury to the government for false marking was a sovereign injury, but held that this injury was sufficient to give the government (and thus the *qui tam* plaintiff) standing to bring an action for false marking.³²

The *Stauffer* case is currently on appeal, and in its brief, the appellant argues that the government has suffered an injury-in-fact.³³ The “injury,” appellant argues, is the thwarting of Congress’ intent for the public to rely on marking as a way to discern the status of intellectual property embedded in an article.³⁴ Under that view, the public deception is the injury-in-fact: because competition has been wrongfully suppressed, harm is caused to the economy of the United States.

Interestingly, the House has recently proposed a patent reform amendment that would essentially require an “injury in fact” more in line with the classic standing requirement.³⁵ In this proposed amendment to § 292(b), only parties who have suffered a “competitive injury as a result of a violation of this section” would be allowed to sue for false marking and to recover damages “adequate to compensate for the injury;” and the recovery would not be shared with the government.³⁶ As currently proposed, this amendment would be retroactive to all cases pending under § 292 as of the date of enactment.³⁷

Intent to Deceive

The elements that must be proven in an action for false marking under § 292 are (1) marking an unpatented article (2) with

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intent to deceive the public.³⁸ According to the Federal Circuit, a party acts with intent to deceive when that party acts with “sufficient knowledge that what it is saying is not so and consequently that the recipient of its saying will be misled into thinking that the statement is true.”³⁹

Courts have differed regarding the requisite intent to deceive when marking with *expired* patents (as opposed to marking with patents that may have *never* covered the article). For example, in the *Solo Cup* case,⁴⁰ the district court held that Solo Cup did not have the requisite intent to deceive the public even though the company knew that many of the patents printed on its plastic cold drink cup lids had long expired. Solo Cup argued that it had no intent to deceive, but rather that it was cost prohibitive to remove the markings from the pertinent molds. The molding equipment for making the lids lasts about fifteen to twenty years, and the patents had expired before the end of the useful life of the equipment. The cost of replacing the equipment ranged from \$500,000 to \$1.5 million. Additionally, Solo Cup argued that its attorneys believed in good faith that removing the markings was unnecessary, and that it relied on that advice. The district court accepted Solo Cup’s argument and found that there was no intent to deceive.⁴¹

In contrast to *Solo Cup*, one district court held that a defendant intended to deceive the public with a decision to begin marking a new product with an expired patent.⁴² Another district court held that the requisite intent to deceive may exist where the defendant updated product packaging after the patent expired, but failed to remove the expired patent markings.⁴³

The *Solo Cup* case is currently on appeal, and the Federal Circuit has an opportunity

to answer some of the questions raised, such as: Is evidence that a manufacturer marks a product with a patent that the manufacturer knows is expired sufficient to prove the existence of an intent to deceive, or is additional evidence necessary? Is there a different standard of culpability for marking a product with expired patents that may have at one time covered the product, as opposed to marking a product with patents that never covered the product?

Marking with Multiple Patents

One requirement of § 292(a) is that the article be “unpatented.” Traditionally, courts have interpreted this section literally, holding that there is no culpable mismarking if the marker lists a number of patents and less than all the patents cover the article marked.⁴⁴ However, some courts have frowned upon this practice.⁴⁵

In view of *Forest* and the number of other new cases filed alleging false marking, could this issue be revisited? The statute is far from clear as to whether marking an article “may be covered by one or more of . . .” (or similar language) may give rise to liability for false marking if each of the listed patents do not in fact cover the article.

Conclusion

The number of lawsuits recently filed indicates that false marking is a matter of exceptional current concern and interest, and that there will be uncharted waters for the courts to navigate. The *Stauffer* and *Solo Cup* cases have been appealed to the Federal Circuit while the *Forest* case is on remand, and these cases will be closely tracked by interested members of the public and patent bar alike.

Editors’ Note

MBHB has created a false marking resource site, which includes pleadings, analysis, and commentary. Visit <http://www.falsemarking.net/> for more information.

Endnotes

1. 35 U.S.C. § 292(a) (2006).
2. *E.g.*, Act of Aug. 29, 1842, ch. 263, sec. 5, 5 Stat. 543.
3. Complaint, *Pequignot v. Solo Cup Co.*, No. 1:07-cv-00897 (E.D. Va. Sept. 5, 2007).
4. Complaint, *Stauffer v. Brooks Brothers, Inc.*, No. 1:08-cv-10369 (S.D.N.Y. Dec. 1, 2008).
5. Complaint, *Pequignot v. Gillette*, No. 1:08-cv-00049 (E.D. Va. Jan. 17, 2008).
6. 590 F.3d 1295 (Fed. Cir. 2009).
7. 179 F. 506 (1st Cir. 1910).
8. The false marking statute currently in force reads: “Whoever marks upon, or affixes to, or uses in advertising in connection with any unpatented article the word ‘patent’ or any word or number importing the same is patented, for the purpose of deceiving the public . . . Shall be fined not more than \$500 for every such offense.” 35 U.S.C. § 292(a) (2006). The statute in force at the time of the decision in *London* similarly read “for every such offense.” 179 F. at 507.
9. *London*, 179 F. at 507.
10. *Id.* at 508.
11. *Forest*, 590 F.3d at 1301.
12. See McDonnell Boehnen Hulbert & Berghoff LLP, False Patent Marking Resources, <http://www.falsemarking.net/date.html> (last visited Apr. 9, 2010) [hereinafter False Patent Marking Resources].
13. *E.g.*, § 292(b) (“Any person may sue for the penalty, in which event one-half shall go to the person suing and the other to the use of the United States.”).
14. “*Qui tam* provisions are designed to set up incentives to supplement government enforcement, and at their best may ‘compare with the ordinary methods as the enterprising privateer does to the slow-going public vessel.’” *U.S. ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 649 (D.C. Cir. 1994).
15. *E.g.*, § 292(b); 31 U.S.C. § 3730(d) (2006). See generally WILLIAM BLACKSTONE, 3 COMMENTARIES *160 (“[O]ne part is given to the king, to the poor, or to some public use, and the other part to the informer or prosecutor . . .”).
16. See 31 U.S.C. § 3730.
17. Fed. R. Civ. P. 24(a)(2); *Pequignot v. Solo Cup Co.*, 640 F. Supp. 2d 714, 727 (E.D. Va. 2009).

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18. See *Forest R. Etling, Inc. v. WeatherSeal, Inc.*, 58 F. Supp. 269, 269–70 (N.D. Ohio 1944).
19. *Victoria-Vogue, Inc. v. Valcourt, Inc.*, 148 F. Supp. 160, 172 (S.D.N.Y. 1956) (“[W]ith the great growth of the corporate form of doing business it would be more realistic to permit a corporate-plaintiff to serve as the plaintiff-informer.”); *Rembrandt Elecs., Inc. v. Spiraling Prods. Co.*, 137 U.S.P.Q. (BNA) 870, 870–71 (E.D.N.Y. 1963); *Trabon Eng’g Corp. v. Eaton Mfg. Co.*, 37 F.R.D. 51, 56 (N.D. Ohio 1964).
20. See Fed. R. Civ. P. 41(a)(1)(A)(ii).
21. See BLACKSTONE, *supra* note 15, at *160 (“[I]f any one hath begun a qui tam, or popular, action, no other person can pursue it; and the verdict passed upon the defendant in the first suit is a bar to all others, and conclusive even to the king himself.”).
22. See generally False Patent Marking Resources, *supra* note 12. For example, SC Johnson has been sued in two different courts for false marking involving the same patent. Compare Complaint at 3–5, *Hungerpiller v. S.C. Johnson & Son, Inc.*, No. 2:10-cv-00290 (N.D. Ala. Feb. 5, 2010), with Complaint at 5–7, *Yarborough v. S.C. Johnson & Son, Inc.*, No. 1:10-cv-00096 (E.D. Tex. Feb. 19, 2010). Similarly, Hunter Fan was sued in two different courts for false marking involving the same patents and the same products. Compare Complaint at 6–8, *Patent Compliance Group, Inc. v. Hunter Fan Co.*, No. 3:10-cv-00359-P (N.D. Tex. Feb. 23, 2010), with *Simonian v. Hunter Fan Co.*, No. 1:10-cv-01212 (N.D. Ill. Feb. 23, 2010).
23. See, e.g., BLACKSTONE, *supra* note 15, at *160 (“[*Qui tam* provisions have] frequently occasioned offenders to procure their own friends to begin a suit, in order to forestall and prevent other actions: which practice is in some measure prevented by a statute made in the reign of a very sharp-sighted prince in penal laws; which enacts, that no recovery, otherwise than by verdict, obtained by collusion in an action popular, shall be a bar to any other action prosecuted bona fide.” (citations omitted)).
24. See, e.g., *Vermont Agency of Natural Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 776–77 (2000).
25. *Id.* at 771.
26. 615 F. Supp. 2d 248 (S.D.N.Y. 2009).
27. *Id.* at 255.
28. *Id.* The Court also denied the government’s attempt to intervene in the action and defend the constitutionality of the statute. The Court held that testing the sufficiency of a complaint against the requirements for standing does not put the “constitutionality of any Act of Congress into question.” *Stauffer v. Brooks Bros.*, No. 08-cv-10369, 2009 WL 1675397, at *3 (S.D.N.Y. June 15, 2009).
29. *Stauffer*, 615 F. Supp. 2d at 254–55 (“Brooks Brothers responds that the alleged injury – which is supported by no additional factual pleadings – is insufficient to establish an injury in fact to the public The Court agrees.”).
30. “It is beyond doubt that the complaint asserts an injury to the United States – both the injury to its sovereignty arising from violation of its laws (which suffices to support a criminal lawsuit by the Government) and the proprietary injury resulting from the alleged fraud.” *Vermont Agency*, 529 U.S. at 771.
31. 640 F. Supp. 2d 714 (E.D. Va. 2009).
32. See *id.* at 728 (“Unlike false claims against the government, misuse of a patent marking does not involve a proprietary injury to the United States that must be vindicated through the actions of private prosecutors; rather, the injury to the United States is only to its sovereignty.”).
33. Brief of Plaintiff-Appellant Raymond E. Stauffer, No. 2009-1428, 2009 WL 4922995 (Fed. Cir. 2009) (citing *SKF USA, Inc. v. U.S. Customs & Border Prot.*, 556 F.3d 1337, 1375 (Fed. Cir. 2009) (Linn J, dissenting)).
34. *Id.* (citing *Clontech Labs., Inc. v. Invitrogen Corp.*, 406 F.3d 1347, 1356–57 (Fed. Cir. 2005)).
35. H.R. 4954, 111th Cong. § 1(a) (2010). A similar amendment to § 292(b) has been proposed as part of a Manager’s Amendment to S. 515, which was originally introduced in March 2009. The Manager’s Amendment reflects the agreement reached amongst bipartisan members of the Judiciary Committee on a number of patent reform issues, including the false marking section of the Patent Act; to date, however, this Manager’s Amendment has not been introduced as a bill to the 111th Congress.
36. H.R. 4954, 111th Cong. § 1(a).
37. *Id.* § 1(b).
38. *Clontech*, 406 F.3d at 1352.
39. *Id.*
40. *Pequignot v. Solo Cup Co.*, 646 F. Supp. 2d 790 (E.D. Va. 2009).
41. *Id.* at 792–94, 798.
42. *DP Wagner Mfg. Inc. v. Pro Patch Sys., Inc.*, 434 F. Supp. 2d 445, 456–57 (S.D. Tex. 2006).
43. *Brinkmeier v. Graco Children’s Prods. Inc.*, – F.Supp.2d –, C.A. No. 09-262-JJF, 2010 WL 545896, at *4 (D. Del. Feb. 16, 2010).
44. E.g., *Santa Anita Mfg. Corp. v. Lugash*, 369 F.2d 964, 968 (9th Cir. 1966); *Ansul Co. v. Uniroyal, Inc.*, 306 F. Supp. 541, 565–66 (S.D.N.Y. 1969).
45. *Hart-Carter Co. v. J.P. Burroughs & Son, Inc.*, 605 F. Supp. 1327, 1342 (E.D. Mich. 1985) (“The inclusion of such irrelevant and expired patent

numbers on Plaintiffs’ name plate could only confuse and mislead”); see also *Pequignot v. Solo Cup Co.*, 540 F. Supp. 2d 649, 654–56 (E.D. Va. 2008) (holding that marking a product with patents and noting that the “product may be covered by one or more . . . patents” may constitute false marking).

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“Notice Pleading” Isn’t What It Used to Be

In 2007, the Supreme Court issued a decision in an antitrust case, *Bell Atl. Corp. v. Twombly*,¹ which at least arguably altered the landscape of notice pleading. Unfortunately, as is often the case with Supreme Court decisions, the scope and impact of *Twombly* and its progeny is not entirely clear, perhaps leaving a trap for the unwary.

In *Twombly*, telephone and internet subscribers sued a group of local carriers, alleging that the carriers engaged in parallel conduct that precluded competitors from entering the market, in violation of § 1 of the Sherman Act. The district court dismissed the complaint, concluding that the allegations alone, absent any alleged facts tending to exclude the possibility of independent self-interested conduct, were insufficient. The Second Circuit reversed, holding that the district court failed to apply the appropriate standard as enunciated in *Conley v. Gibson*,² i.e., that in order for the complaint to fail on a motion to dismiss, there would have to be “no set of facts” that would permit the subscribers to demonstrate that the parallel conduct was founded in collusion rather than coincidence.

The Supreme Court reversed, holding that the complaint must set forth sufficient facts to provide “plausible grounds” to infer an agreement among the carriers, rejecting the widely used “no set of facts” phraseology of *Conley*. In the years immediately following *Twombly*, courts struggled to assess the actual extent of its holding. Some courts tried to limit it to antitrust cases, while others went to great lengths to try to figure out whether it really imposed a new obligation, or whether it simply explained what Rule 8(a) meant in saying that a pleader must provide “a short and plain statement of the claim showing that the pleader is entitled to relief . . .”

Two years later, in 2009, the Supreme Court decided *Ashcroft v. Iqbal*,³ which clarified some, but not all, of the outstanding questions regarding *Twombly*’s holding. Significantly, *Iqbal* confirmed that the pleading standard enunciated in *Twombly*—that although Rule 8 “does not require ‘detailed factual allegations,’” it nevertheless “demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation”⁴—applied to “all civil cases,”⁵ not just antitrust litigation.⁶ Additionally, *Iqbal* reaffirmed the teachings of *Twombly* that a

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A cautious litigant should include at least some general facts supporting his or her patent litigation claims, lest they fall victim to a motion to dismiss for failure to state a claim.

claim must provide sufficient factual detail to plausibly infer that the claimant has a right to relief.⁷ Thus, a pleading must set forth a factual basis sufficient to plausibly support the party’s claims and defenses; mere conclusions are insufficient.

More specifically, *Iqbal* set forth a two-pronged test for whether a complaint can withstand a motion to dismiss under *Twombly*:⁸ First, the pleading must be analyzed to determine which allegations are nothing more than conclusions and are therefore not entitled to an assumption of truth. As *Iqbal* notes, the tenet that allegations contained in a complaint must be accepted as true is inapplicable to legal conclusions. Second, the remaining, well-pled facts, which are to

be accepted as true, are to be analyzed to determine whether they plausibly support an entitlement to relief.

While *Iqbal* set forth a framework for assessing whether a complaint has been properly pled, the specific requirements to avoid dismissal of a complaint under *Twombly* remain unclear. As the Supreme Court noted, “[d]etermining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.”⁹ Other courts have noted that *Twombly*’s is a shifting standard, requiring more explanation and facts in some types of claims or defenses than in others.

So what is the practical impact of these decisions on patent litigation? In short, it can be expected that a bare-bones pleading of “the defendant infringes under 35 U.S.C. § 271” will be met with a motion to dismiss/strike, as will counterclaims and affirmative defenses that state nothing more than:

- a patent is “not infringed;”
- a patent is “invalid under 35 U.S.C. §§ 102, 103 and/or 112;” and/or
- a claim “is barred by waiver, laches, estoppel and/or unclean hands.”

Yet the question remains: what is enough? Some courts have interpreted *Twombly* and *Iqbal* as requiring nothing more than that which is provided for in Form 18 of the Federal Rules of Civil Procedure (“Given [the] language [of *Iqbal*], and the practical difficulties of pleading patent infringement with more specificity than that required by Form 18, it is evident that *Iqbal* does not require the degree of specificity demanded by [the defendant]).¹⁰ Conversely, other courts have found complaints to be insufficiently pled for failing to specifically allege facts that plausibly
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“Notice Pleading” Isn’t What It Used to Be

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bly established, for indirect infringement, the required elements of intent and knowledge, and for contributory infringement, that the defendant knows its product to be especially designed for use to infringe.¹¹

One noteworthy decision is *Aspex v. Clariti*,¹¹ in which the court dismissed bare-bones counterclaims and struck affirmative defenses in a patent case:

Clariti merely asserts these claims and defenses without alleging even general facts to support them. In fact, Clariti asserts **no** facts, nor does Clariti even refer to the elements of the various affirmative defenses. Mere conclusory assertions are not sufficient to give plaintiffs notice of the counterclaims and defenses and, thus, do not meet Rule 8(a)’s pleading standards. Accordingly, plaintiffs’ motion to strike certain affirmative defenses and dismiss certain counterclaims is granted.¹³

Notably, Congress has gotten involved; bills have been introduced in the House and Senate to reverse the *Twombly* and *Iqbal* decisions.¹⁴ In the meantime, however, the courts are left to figure out how to apply these decisions to patent infringement claims and related counterclaims and affirmative defenses. A cautious litigant, therefore, should include at least some general facts supporting his or her patent litigation claims, lest they fall victim to a motion to dismiss for failure to state a claim.

Endnotes

1. 127 S. Ct. 1955 (2007).
2. 355 U.S. 41 (1957).
3. 129 S. Ct. 1937 (2009).
4. *Id.* at 1949.
5. The Court of Appeals for the Federal Circuit had already determined, prior to *Iqbal*, that *Twombly* applied outside of the context of antitrust litigation. Specifically, in *McZeal v. Sprint*, 501 F.3d 1354 (Fed. Cir. 2007), the Federal Circuit, in the context of a

patent and trademark infringement action, endorsed the holding of *Twombly* as setting forth the pleading requirements under the Federal Rules of Civil Procedure. The Federal Circuit noted, however, that a motion to dismiss for failure to state a claim upon which relief can be granted is a procedural question not pertaining to patent law and thus falls within the ambit of the law of the regional circuit.

6. 129 S. Ct. at 1953.
7. *Id.* at 1949.
8. *Id.* at 1949-50.
9. *Id.* at 1950.
10. *Mark IV Indus. Corp. v. Transcore, L.P.*, 2009 U.S. Dist. LEXIS 112069 (D. Del. Dec. 2, 2009). See also *Davis-Lynch, Inc. v. Hilcorp Energy Co.*, 2009 U.S. Dist. LEXIS 125393 (E.D. Tex. Nov. 18, 2009).
11. *R&L Carriers, Inc. v. Affiliated Comp. Servs., Inc.* (In re Bill of Lading Transmission & Processing Sys. Patent Litig.), 2010 U.S. Dist. LEXIS 16110 (S.D. Ohio Feb. 23, 2010). See also *Mallinckrodt, Inc. v. E-Z-EM Inc.*, 2009 U.S. Dist. LEXIS 108696 (D. Del. November 20, 2009).
12. 531 F. Supp. 2d 620 (S.D.N.Y. 2008).
13. *Id.* at 623 (internal citations omitted, emphasis in original).
14. See H.R. 4115 (“Open Access to Courts Act of 2009”) and S. 1504 (“Notice Pleading Restoration Act of 2009”).

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