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A review of developments in Intellectual Property Law

Review of Section 101 Decisions by the Federal Circuit

By Sydney R. Kokjohn and Adnan "Eddie" M. Obissi

Since the Supreme Court decided *Alice Corp. v. CLS Bank Int'l* in 2014, patent practitioners and the courts alike have struggled to find clarity in the patent eligibility framework of 35 U.S.C. § 101. For the Federal Circuit in particular, applying the two-step framework set forth in *Mayo Collaborative Servs. v. Prometheus Labs., Inc*. and *Alice* with any consistency has proven difficult, as the lines between abstract and non-abstract ideas, between step one and step two of the framework, and between eligibility (§ 101) and patentability (§§ 102, 103, or 112) have grown fainter. This summer, the Federal Circuit decided nine cases concerning patent eligibility under 35 U.S.C. § 101.[1] This article provides an overview of these decisions, as well as a discussion of the highlights from, and implications of, the Federal Circuit's opinions that found the claims eligible.

The now-familiar *Alice* framework for determining patent eligibility first asks the court to determine whether the claims are "directed to" a patent-ineligible concept (e.g., an abstract idea, law of nature, or natural phenomenon).[2] The second step is to determine whether the claims also supply an "inventive concept" such that the claim limitations, individually or as an ordered combination, amount to significantly more than a patent on the ineligible concept itself.[3] The decisions listed below each applied this framework.

Step 1 – Determining Whether a Claim is "Directed To" Ineligible Subject Matter

While most decisions since *Alice* have simply found an ineligible concept at step one, three decisions this summer discussed the first step of the *Alice* analysis in detail.

In *Enfish*, the Federal Circuit noted that "claims purporting to improve the functioning of the computer itself, or improving an existing technological process might not succumb to the abstract idea exception."[4] Thus, a relevant inquiry in step one is whether the invention improves the operation of a computer or a technological process. Conducting this analysis, the court rejected Microsoft's notion that claims were directed to "the concepts of organizing data into a logical table with identified columns and rows," noting that "describing the claims at such a high level of abstraction and untethered from the language of the claims all but ensures that the exceptions to § 101 swallow the rule."[5] Instead the court looked to the teachings of the specification to conclude that the invention involves an improvement to an existing technology that exhibits "benefits over conventional databases, such as increased

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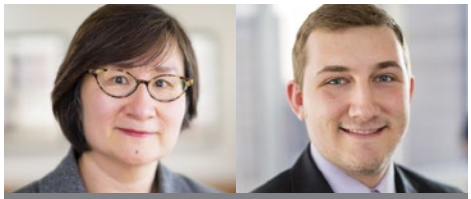
Lessons Learned from AIA Invalidity Proceedings in the Bio/Pharma Space



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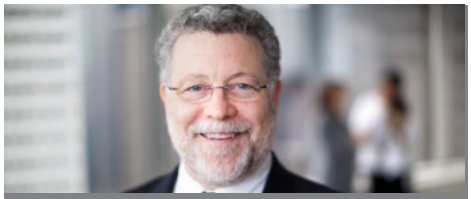
Tiffany vs. Costco: Jury Awards Tiffany Substantial Damages



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The Failed Trans-Pacific Partnership: What It Might Have Meant To Biotech and Pharma

mbhb McDonnell Boehnen Hulbert & Berghoff LLP
Intellectual Property Law

Case	Date	Step 1	Step 2
Enfish, LLC v. Microsoft Corp.	May 12	The claims were not abstract because they recited a specific type of self-referential database table	N/A
Bascom-Global Internet Services, Inc. v. AT&T Mobility LLC	June 27	The claims were directed to the abstract idea of filtering content	The non-conventional arrangement of the limitations provided an inventive concept
Rapid Litigation Management Ltd. v. CellzDirect, Inc.	July 5	The claims were not directed to an ineligible law of nature	The claims improved an existing technological process, and included steps that were not "routine or conventional," and thus would provide an inventive concept
Shortridge v. Foundation Construction Payroll Service, LLC	July 13	The claims were directed to the abstract idea of cataloging labor data	The other limitations in the claims merely recited conventional and known computer components, a mathematical algorithm, and field of use limitation
Lending Tree, LLC v. Zillow, Inc.	July 25	The claims were directed to the abstract idea of coordinating loans	The other limitations in the claims simply automated a fundamental economic concept using generic-computer functions
Electric Power Group, LLC v. Alstom S.A.	August 1	The focus of the claims was on collecting and analyzing data, and displaying results	The other limitations merely limited the claims to a particular technological environment, and used conventional computer, network, and display components
In re Chorna	August 10	The claims were directed to the abstract idea of hedging and intermediated settlement	The other limitations merely added conventional steps and a field of use limitation, used a computer to issue automated instructions, and sent/received information over a network
TDE Petroleum Data Solutions, Inc. v. AKM Enterprise, Inc.	August 15	The claims recited data gathering and processing performed by a general-purpose computer	The other limitations, individually or as an ordered combination, did not provide anything more than the abstract idea of storing, gathering, and analyzing data
McRo, Inc. v. Bandai Namco Games America Inc.	September 13	The claims were directed to a specific, technological improvement in computer animation	N/A

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flexibility, faster search times, and smaller memory requirements."[6]

In *CellzDirect,*[7] the Federal Circuit discussed what "directed to" actually means. The court explained that "[i]n recent cases, we found claims 'directed to' a patent-ineligible concept when they amounted to nothing more than observing or identifying the ineligible concept itself."[8] The court found the claims eligible at step one, determining that, while the claims achieved a desired result, and utilized a law of nature (a liver cell's ability to survive multiple freeze-thaw cycles) to achieve that result, they were not "directed to" the law of nature itself. Rather, the claims were "directed to a new and useful method of preserving [liver] cells."[9] Though the defendant argued that the court's careful analysis of whether the claimed invention was "directed to" ineligible subject matter improperly shoehorned step two of the analysis into step one, the court stated that "an invention is not rendered ineligible for patent simply because it involves one of the patent-ineligible concepts."[10] The court also warned that over-application of the judicial exceptions to § 101 would "eviscerate patent law."[11] This response reminds us that "the [step one] filter is a meaningful one," and "the two [steps] involve overlapping scrutiny to the content of the claims."[12] As such, the court made it clear that step one does not end after identifying a patent-ineligible concept that underlies a claim, but rather requires that one "determine whether that patent-ineligible concept is what the claim is directed to."[13]

The *McRO* decision similarly focused on the first step of *Alice* in its analysis. In *McRO,* the court started by warning against oversimplifying the claims "by looking at them generally and failing to account for the specific requirements of the claims."[14] As in *Enfish* and *CellzDirect,* the *McRO* court seemed to acknowledge that its step one analysis overlapped with step two. The court noted that "[w]hether at step one or step two of the *Alice* test, in determining the patentability of

a method, a court must look to the claims as an ordered combination, without ignoring the requirements of the individual steps."[15] And, as in *Enfish* and *CellzDirect,* the court in *McRO* found it significant that the claims recited an improvement over the art.[16] Specifically, the claims improved the prior art through "the use of rules, rather than artists,"[17] to perform lip-synchronized three-dimensional animation. As such, the claim was a specific process that did not preempt other approaches to automatically animating characters. Rather, when viewed as a whole, the claims were "directed to a patentable, technological improvement over the existing, manual 3–D animation techniques."[18] The *McRO* court explained that one should determine "whether the claims in these patents focus on a specific means or method that improves the relevant technology or are instead directed to a result or effect that itself is the abstract idea."[19] Thus, patent applicants should claim the "specific means" of improving a relevant technology, rather than the "result or effect," of those means.[20]

Step 2 – Determining Whether the Claim Adds "Significantly More"

In *Bascom,* the court also found the claims to be inventive, but at step two rather than at step one.[21] Here, the court noted that the step one/step two distinction is particularly blurry in software-related patents. The court wrote that "some inventions' basic thrust might more easily be understood as directed to an abstract idea, but under step two of the *Alice* analysis, it might become clear that the specific improvements in the recited computer technology go beyond 'well-understood, routine, conventional activities' and render the invention patent-eligible."[22] The court identified the lower court's step two analysis as resembling a § 103 rejection, "except lacking an explanation of a reason to combine the limitations as claimed,"[23] and clarified that step two does not amount to recognizing that each claim element was known in the art. Rather, "an inventive concept can be found in the non-conventional and non-generic arrangement of known, conventional pieces."[24] In this case, that inventive concept involved "taking advantage of the ability of at least some [Internet service providers (ISPs)] to identify individual accounts that communicate with the ISP server, and to associate a request for Internet content with a specific individual account,"[25] to achieve the benefits associated with filtering content on one's personal computer without the drawback of allowing that user to modify that filtering. The court focused on the fact that the claims recited a "discrete implementation," of an abstract idea to achieve a technical improvement, rather than simply reciting "the abstract idea of filtering content along with the requirement to perform it on the Internet, or to perform it on a set of generic computer components."[26] In this way, the step two analysis in *Bascom* is similar to the step one rationale in *CellzDirect* or *McRO:* each set of eligible claims recited a "specific means" of improving the relevant technology, rather than reciting the "result or effect" of those means. Stated differently, they each "took advantage of" the ineligible concept to achieve the desired result, rather than directing the claims to effectively preempt others from utilizing that concept themselves.

While most decisions since *Alice* have simply declared an ineligible concept at step one, three decisions this summer discussed the first step of the *Alice* analysis in detail.

Implications Moving Forward

The cases decided by the Federal Circuit this summer have shown that this court is willing to acknowledge the blending of steps one and two of the *Alice* inquiry. The decisions have also noted similarities and differences between the § 101 analysis and those of §§ 102, 103, or 112. Also, whether decided at step one or step two of the *Alice* inquiry, the cases remind us that the judicial exceptions to § 101 are ultimately about preemption of basic scientific and technological tools. Thus, claims should be drafted concretely to utilize an abstract idea, law of nature, or natural phenomenon as a means to a specific useful end, rather than as an aspirational goal that preempts all other useful applications of a patent-ineligible concept.

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Endnotes

1 We include a case from May in the list of decisions that came down this "summer." We do this because (i) that particular case *(Enfish, LLC v. Microsoft Corp.)* has been very influential, and (ii) this past May was unusually warm and summer-like.
2 Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S.Ct. 2347, 2355 (2014).
3 *Id.* (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.,* 132 S.Ct. 1289, 1298 (2012)).
4 Enfish, LLC v. Microsoft Corp., 822 F.3d 1327, 1335 (Fed. Cir. 2016).
5 *Id.* at 1337.
6 *Id.*
7 Rapid Litigation Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042 (Fed. Cir. 2016).
8 *Id.* at 1048.
9 *Id.*.
10 *Id.* at 1050 (quoting *Alice,* 134 S.Ct. at 2354).
11 *Id.* (quoting Mayo, 132 S.Ct. at 1293).
12 Electric Power Group, LLC v. Alstom S.A., 830 F.3d 1350, 1353 (Fed. Cir. 2016).
13 *CellzDirect,* 827 F.3d at 1050.
14 McRO, Inc. v. Bandai Namco Games Am. Inc., No. 2015-1080, 2016 WL 4896481, *7 (Fed. Cir. Sept. 13, 2016).
15 *Id.*
16 *Id.* at *8.
17 *Id.*
18 *Id.* at *10.
19 *Id.* at *8.
20 *Id.*
21 Bascom Global Internet Servs., Inc. v. AT&T Mobility LLC, 827 F.3d 1341 (Fed. Cir. 2016).
22 *Id.* at 1348 (quoting *Alice,* 134 S.Ct. at 2359).
23 *Id.* at 1350.
24 *Id.*
25 *Id.*
26 *Id.*

Lessons Learned from AIA Invalidity Proceedings in the Bio/Pharma Space

By Alison J. Baldwin and Paula S. Fritsch, Ph.D.

September 16, 2016, marked the fourth anniversary of the effective date for the invalidity proceedings before the Patent Trial and Appeal Board (PTAB or Board) created by the America Invents Act (AIA). These new AIA proceedings, particularly covered business method reviews (CBM) and *inter partes* reviews (IPR), had an almost immediate impact on litigation defense strategies in the financial services and technology fields.

The impact in the bio/pharma field was slower at the beginning, but the number of AIA petitions for review of bio/pharma patents has steadily increased over the past four years. In fiscal year (FY) 2016, bio/pharma patents have accounted for 14% of the 1,529 AIA petitions filed at the U.S. Patent and Trademark Office (PTO).[1] This is an increase from 9% in FY 15 and 6% in FY 14.[2] The increased and more routine use of these AIA invalidity proceedings in the bio/pharma field is having an impact on even the highly regulated areas of Hatch-Waxman drug (ANDA) and biosimilar patent litigation.

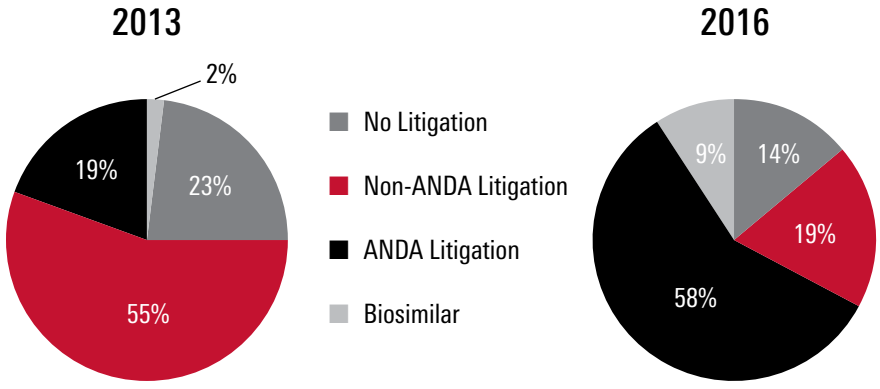
Who Is Using PTAB Proceedings to Challenge Bio/Pharma Patents?

A review of the bio/pharma AIA petitions[3] filed in 2013 and 2016 provides insight into how AIA petitions have influenced litigation strategies. As shown in the Figure below, there has been a dramatic shift in the way AIA petitions are being used to challenge bio/pharma patents.

In 2013, the majority of the petitions were filed on litigated patents (approximately 75%), but many more of those petitions challenged patents involved in non-ANDA litigations (approximately 55%) than ANDA litigations (approximately 19%). In 2016, while petitions have again primarily been filed to challenge patents that are in litigation (approximately 80%), there has been a significant shift in the type of related litigation. Indeed, the percentage of petitions challenging patents that are involved in (or have been involved in) ANDA litigations versus non-ANDA litigations flipped in 2016 as compared to 2013.

The decrease in the percentage of petitions filed on bio/pharma patents that are involved in non-ANDA litigations was not due to a decline in the filings of such petitions. Indeed, the number of petitions filed for such patents remained the same in 2013 to 2016 (26 petitions in each year). Rather, the overall percentage decrease for challenges to patents involved in non-ANDA litigations was primarily due to a significant increase in the number of petitions challenging patents involved in ANDA litigations – up from 9 in 2013 to 82 so far in 2016.

Although more challenges in the ANDA context in 2016 were filed by petitioners that do not appear to be the first ANDA filers (approximately 43%), the apparent first ANDA filers have also filed a significant number of petitions (approximately 27%). Interestingly, the remaining 30% of the petitions filed in 2016 challenging patents involved in ANDA litigations have been filed by petitioners that are not involved in the related ANDA litigations.



Many of these petitioners have been parties in other ANDA litigations, so those petitioners could be pursuing FDA approval for the drugs at issue in those ANDA litigations under a certification that they will not launch until the Orange Book patents covering the product expire (a Paragraph III certification).

There also has been an increase in challenges to patents related to biologics – up from 1 in 2013 (2%) to 12 already in 2016 (9%) – but, at present, few of those patents have been challenged in biosimilar litigation. Time will tell if petitions will continue to be filed at the current pace, and if there will be a further redistribution of the types of patents challenged as biosimilar litigation ramps up.

Lessons Learned

The influence of AIA proceedings on bio/pharma litigation was addressed in an MBHB webinar,[4] but there are certainly a number of takeaways that can be gleaned from the AIA petitions that have been filed over the past four years involving bio/pharma patents.

For the Petitioner

The Petition

The petition is the petitioner's first chance to impress upon the Board that the challenged claims should have never issued. As a practical matter, petitioners that have been served with a complaint for patent infringement need to be sure to have their petition on file within one year of being served with the complaint,[5] as the Board strictly enforces that deadline.[6] In addition, care should be taken to ensure that the petition includes all required information, as petitions have frequently been rejected on procedural grounds for failure to provide necessary information.[7] With respect to the grounds in the petition, there is a higher likelihood of institution (and ultimately, cancellation) based on obviousness challenges than on anticipation challenges. And if the petition relies on the same reference for both anticipation and obviousness grounds, there is a better chance of institution on the obviousness challenge than for anticipation. Finally, given the word count limits,[8] it may

be better to file multiple petitions to fully address multiple grounds for challenging the patent rather than shortchanging some of the grounds in order to fit within the limits of a single petition. This option is more costly since multiple request fees would be due,[9] but pre-paid post-institution fees can be recovered via a request for refund if the Board does not institute review of one (or more) of the petitions, or if the Board institutes review for fewer claims than requested.[10]

Request for Rehearing

A petitioner can seek rehearing following a decision denying institution,[11] but to date, such requests have rarely been successful. Indeed, it is not uncommon for the Board to use the request as a means to amend or revise the Institution Decision based on the petitioner's comments in the request. A request for rehearing can also be filed following an unfavorable Final Written Decision, but again, such requests are rarely successful. Thus, a petitioner should weigh the potential benefits (and the likelihood of achieving those benefits) against the costs associated with making such requests.

Motion for Joinder

A motion for joinder allows would-be petitioners who missed the "one-year from being served with an infringement complaint" window to join an instituted IPR, provided that such a motion is filed within one month of the institution decision in the IPR for which joinder is requested.[12] To expedite the decision on the motion for joinder and to increase the likelihood that the motion will be granted, the movant's own IPR petition (which is filed with the motion) should track the instituted grounds and omit any uninstituted grounds or any additional grounds. In addition, the movant should reach out to the original petitioner as early as possible to discuss coordination of efforts, and attempt to reach agreement on how the parties will coordinate efforts before filing the motion, if possible.[13]

Opposition to Amendment

Following institution, the patent owner can seek permission from the Board to file a motion to amend.[14] However, a recent study from the PTO indicates that few patent owners have successfully amended claims in AIA proceedings, due at least in part to the high burden on the patent owner to show, by a preponderance of the evidence, the patentability of the proposed substitute claims.[15] If faced with a motion to amend, a petitioner should consider all avenues of attack, including whether the patent owner has met its burden of demonstrating that the proposed claims overcome all the prior art at issue, meet all the other requirements for patentability, and do not enlarge the scope of the claims of the patent or introduce new subject matter.[16]

For the Patent Owner

Experts

Technical expert witnesses play a critical role in patent litigation in district court. These experts provide testimony to assist the court in understanding the invention, including how it works and its real-world implications. Most importantly, these technical expert witnesses assist the Court in placing itself in the shoes of the hypothetical person of ordinary skill in the art to understand the teachings of the prior art at the time of the invention.

The impact in the bio/pharma field was slower at the beginning, but the number of AIA petitions for review of bio/pharma patents has steadily increased over the past four years.

While technical expert witnesses play a similar role in AIA proceedings, the strategies for presenting an expert witness's testimony are different in such a setting, where the testimony is presented almost entirely through written declarations and deposition testimony and not through the presentation of a live witness. For a patent owner, one critical strategy decision is when to utilize expert testimony in the AIA proceedings. As of May 2016, patent owners may submit expert testimonial evidence with the patent owner's preliminary response.[17] While it may be too soon to reach any significant conclusions, we did not observe any noticeable impact on the likelihood of denial of institution based on the use of an expert declaration in the patent owner's preliminary response. This may be due to the fact that, at the institution stage, deference is given to the petitioner in the event of a disagreement between the opinions of the two competing experts (which will almost always be the case). Since it is unlikely that a patent owner's expert will win the battle of the expert testimonials at the institution stage of the proceedings, serious consideration should be given to foregoing expert testimony at the preliminary response stage. If there is a compelling reason to use expert testimony in that preliminary response, it is advised to limit the expert's testimony according to the specific need, as using an expert could lock the expert into a position unnecessarily early in the proceedings.

Secondary Considerations

Objective indicia of non-obviousness (aka secondary considerations) play an important role in the obviousness analysis in district court. This is not surprising, particularly in ANDA litigation, because the patented product is often a drug product or method of treatment that has achieved commercial success because it fills a previously unmet treatment need for a population of patients. But do these secondary considerations carry any weight in the Board's decision to institute? The answer is no. Because deference is given to the petitioner in the Board's institution decision, at best, the Board will acknowledge the patent owner's preliminary evidence of secondary considerations and note that they will wait to determine the weight of that evidence once the record is complete.[18]

If secondary considerations carry so little weight in the institution decision, will they carry more weight in the Board's ultimate obviousness analysis at final written decision? The answer to that question is also no, but for a very different reason. Often the evidence of secondary considerations is based upon the clinical studies and success of the commercial product. At the district court level, this is effective because the claims at issue have often been narrowed to those that specifically encompass the labeled drug product and the

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infringing generic version of that product. In contrast, the claims under review in the IPR proceeding often include the broadest claims. Therefore, the PTAB often holds that the secondary consideration evidence presented does not overcome the petitioner's *prima facie* case of obviousness because the evidence either lacks the requisite nexus with the claims and/or is not commensurate in scope with the broadest claims under review.[19]

One strategy to increase the weight and effectiveness of secondary consideration evidence is to cancel the broadest claims under review in favor of narrower claims (already in the patent or added by amendment) that specifically encompass the commercial embodiment of the claimed product. While, as a rule, amendment practice has been met with almost no success, this is a situation where amendment might pay off (if all of the other amendment requirements can be met), as it would create a situation more akin to how secondary considerations evidence is traditionally presented to and considered by a district court. A second strategy is to present the secondary consideration evidence on a claim-by-claim basis, in recognition that the secondary consideration evidence may not be equally applicable to all of the challenged claims. Presenting the secondary consideration evidence in a claim-by-claim manner instead of generally should help ensure that the evidence corresponds to the scope of the challenged claim.

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Endnotes

1 Data from the PTO website, available at https://www.uspto.gov/sites/default/files/documents/2016-08-31%20PTAB.pdf. The data is current as of August 31, 2016, but is not reflective of the entire FY 16, which ended September 30, 2016. The PTO classifies Bio/Pharma patents as those in Technology Center 1600.
2 *Id.*
3 We reviewed petitions for IPR and post-grant review (PGR) filed for patents within Classes 424 and 514 (Drug, Bio-Affecting and Body Treating Compositions) of the U.S. Patent Classification System. For 2016, we reviewed the petitions filed through October 14.
4 *See* Alison Baldwin and Paula Fritsch, Ph.D., The Shifting Landscape of Bio/Pharma Litigation: The Influence of PTAB Proceedings, MBHB Webinar (September 20, 2016), available at http://www.mbhb.com/events/xpqEventDetail.aspx?xpST=EventDetail&event=203.
5 35 U.S.C. § 315(b); 37 C.F.R. § 42.101(b).
6 *See, e.g.,* IPR2014-00361, Paper 14, and IPR2016-00282, Paper 19.
7 *See, e.g.,* IPR2014-01422, Paper 14, denying institution for failure to name all real parties in interest, where allowing the petitioner to cure the defect would be futile because the corrected petition would be untimely.
8 37 C.F.R. § 42.24.
9 37 C.F.R. § 42.15.
10 *See* https://www.uspto.gov/patents-application-process/appealing-patent-decisions/trials/patent-review-processing-system-prps-0 at E7.
11 37 C.F.R. § 42.71(c).
12 37 C.F.R. § 42.122(b).
13 *See, e.g.,* IPR2016-01122, Papers 10, 12-14, where the second petitioner's petition copied the instituted grounds from the IPR for which joinder was requested, but the second petitioner and the original petitioner had not reached agreement on coordination amongst the parties at the time the second petition and the motion for joinder were filed, which led the patent owner to initially oppose the motion for joinder. That opposition was withdrawn once the petitioners reached a coordination agreement.
14 37 C.F.R. § 42.121.
15 Patent Trial and Appeal Board Motion to Amend Study, available at https://www.uspto.gov/sites/default/files/documents/2016-04-30%20PTAB%20MTA%20study.pdf.
16 *See* 37 C.F.R. § 42.121; *Nike, Inc. v. Adidas AG,* 812 F.3d 1326, 1334 (Fed. Cir. 2016) ("[T]he Board did not err by placing the burden on [Patent Owner] to establish patentability over the prior art of [Patent Owner]'s proposed substitute claims.").
17 Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board, Federal Register, Vol.81, No. 63, Friday, April 1, 2016.
18 *See, e.g.,* IPR2013-00371, Paper 11.
19 *See, e.g.,* IPR2014-00784/IPR2015-00518, Paper 112.

Tiffany vs. Costco: Jury Awards Tiffany Substantial Damages for Costco's Sale of Counterfeit Diamond Rings

By Emily Miao, Ph.D. and Daniel L. Organ

In a highly publicized decision of over a year ago,[1] Judge Swain of the U.S. District Court of the Southern District of New York ruled in favor of the luxury retailer Tiffany and Co., deciding that Costco Wholesale Corp., the largest U.S. warehouse club chain, willfully infringed Tiffany's trademark. According to the court, Costco sold counterfeit diamond engagement rings bearing the Tiffany name and confused consumers by using the word "Tiffany" in display case signage. The court rejected Costco's fair use defense and assertion that "Tiffany" is a generic description of a type of ring setting. Judge Swain's initial ruling against Costco allowed Tiffany to take Costco before a jury to seek damages, including recovery of Costco's profits from the sale of the diamond rings, statutory damages, and punitive damages.

After several delays, the jury finally met at the end of September for "Phase I" of the trial during which they decided (1) the amount of Costco's profits and statutory damages under the Federal Lanham Act, and (2) whether Tiffany was entitled to punitive damages under New York General Business Law § 349 and New York Common Law. "Phase II" was triggered when the jury found Costco liable for punitive damages. In their Phase I verdict, the jury determined that Costco profited by $3.7 million from the infringing sales, but decided that this amount was inadequate to compensate Tiffany, and added an additional $1.8 million bringing the total award for profits to $5.5 million.[2] The jury also awarded $2 million for statutory damages.[3] The jury further decided that Tiffany was entitled to punitive damages, and in the "Phase II" verdict awarded Tiffany an additional $8.25 million in punitive damages.[4]

Analysis of Costco's Profits

Tiffany had originally sought an accounting of profits based on the sale of both "non-subject goods" (*e.g.,* Costco memberships and goods other than diamond rings) and "subject goods" (*e.g.,* diamond rings). Under Second Circuit law, in calculating "defendant's profits," a court is to base its analysis on "infringing sales," or on sales that can in some way be tied to the Lanham Act violation alleged.[5] The court held that Tiffany presented no evidence tying the "non-subject goods" to Costco's alleged infringement of the Tiffany mark, and therefore granted Costco's motion to strike the demand for an accounting on non-subject goods. Regarding the "subject goods," however, the court held that Costco did not act in good faith and therefore Tiffany would be allowed to seek an accounting for profits from the sale of subject goods.[6] The court's decision paved way

for the jury to decide, in a damages phase of the trial, whether or not Tiffany was entitled to damages for Costco's unlawful use of Tiffany's mark.

During the damages trial, Tiffany argued that it was entitled to millions in damages from profits realized by Costco, while Costco asserted that the amount based on actual sales would be no more than $382,000.[7] The Jury disagreed with Costco, and awarded Tiffany $5.5 million based on Costco's profits.

Analysis of Statutory Damages

In addition to awarding Costco's profits, the jury awarded Tiffany statutory damages in the amount of $2 million. The Federal Lanham Act states that when a counterfeit mark is used, up to $2 million may be awarded for a willful violation, the exact amount depending on what the court considers just.[8] In Judge Swain's initial ruling, the court held that, as a matter of law, Costco used a counterfeit mark, and that Tiffany had satisfied the willfulness requirement.[9] The jury was then instructed to consider factors such as Costco's profits reaped, Tiffany's lost revenue, the value of the mark, the deterrent effect on others, and whether Costco's conduct was innocent or willful, among others.[10] As a result, the jury in "Phase I" of the damages trial determined that the maximum $2 million in statutory damages was justified.

Analysis of Punitive Damages

Tiffany originally sought punitive damages based on Costco's alleged infringement under both Federal and State law. Under Federal law, the court held that the Lanham Act prevents the collection of punitive damages.[11] Under State law, however, the court noted that New York General Business Law § 349 and New York Common Law allow punitive damages, albeit with an exceptionally high bar.[12] Under these laws, "punitive damages are available where a defendant's conduct has constituted gross, wanton or willful fraud or other morally culpable conduct to an extreme degree."[13] In the court's opinion, evidence in Tiffany's favor in this respect included emails sent from Costco jewelry buyers asking vendors to copy Tiffany designs, and testimony indicating that Costco employees were aware of customer confusion but did nothing to remedy it.[14]

The jury ultimately agreed with Tiffany, and in "Phase II" of the damages trial, decided to award Tiffany $8.25 million in punitive damages.

Conclusion

After the initial ruling, Judge Swain set a pre-trial conference for November 3, 2015, and directed Tiffany and Costco to "make good faith efforts to settle the outstanding issues." But since no settlement between the contentious parties occurred, the damages phase of the trial proceeded and the jury handed a sweeping victory to Tiffany with a total award of nearly $16 million in damages.

Tiffany has been involved for many years in lawsuits regarding its intellectual property. A recent search of the public court records database PACER returned 28 lawsuits since 1991 involving Tiffany copyrights, patents, and trademarks. While the award of nearly $16 million against Costco is one of Tiffany's largest awards, Tiffany previously won a default judgment in the amount of $26.5 million against numerous defendants for infringement of Tiffany trademarks and for using infringing internet domain names. Many of Tiffany's other lawsuits have ended in settlement or relatively minor damages awards.

In addition to awarding Costco's profits, the jury awarded Tiffany statutory damages in the amount of $2 million.

Costco is also no stranger to lawsuits regarding intellectual property issues, both as a plaintiff and (more often) as a defendant. A recent search of PACER returned 190 lawsuits over intellectual property issues since 1991, comprising 47 trademark suits of which Costco was a defendant in 36 cases; 119 patent suits of which Costco was a defendant in 102 cases; and 24 copyright suits of which Costco was a defendant in 22 cases.

Tiffany has a history of policing its trademarks,[15] in particular with respect to certain goods such as its jewelry,[16] its well-known blue gift boxes, cufflinks, and money clips.[17] But Tiffany has not policed its marks with respect to engagement rings until now. Because the facts in this case were straightforward and favorable to Tiffany, it is not surprising that Tiffany won. Had Tiffany lost, there would have been inherent confusion around the use of the TIFFANY mark as applied to diamond rings and ring settings. Such a result would have been contrary to one of the purposes of trademark protection, which is to avoid consumer confusion.[18]

With the conclusion of the damages trial and assuming that Judge Swain accepts the jury's findings, it is likely that Costco will file an appeal against Judge Swain's ruling as well as the damages award. Stay tuned for further developments.

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Endnotes

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10 Memorandum to Counsel at 24-25, Tiffany and Co. v. Costco Wholesale Corp., No. 13CV1041-LTS-DCF (S.D.N.Y. Sept. 27, 2016).
11 *Tiffany and Co.*, 127 F. Supp. 3d at 261.
12 *Id.*
13 *Id.* (citing Altadis U.S.A., Inc. v. Monte Cristi de Tabacos, c.x.a., No. 96CV4209-BSJ, 2001 U.S. Dist. LEXIS 6892 (S.D.N.Y. May 17, 2001)).
14 *Tiffany and Co.*, 127 F. Supp. 3d *at 262*.
15 For example, in 2006 Tiffany had an employee dedicated to monitoring listings on the eBay website for counterfeits and to reporting any violations to eBay on a daily basis. *See Tiffany (NJ) Inc. v. eBay, Inc.*, 576 F. Supp. 2d 463, 484 (S.D.N.Y. 2008) *aff'd in part, rev'd in part sub nom. See also* Complaint at ¶ 17 (describing other brand protection strategies).
16 *See* Tiffany (NJ) Inc. v. Luban, 282 F. Supp. 2d 123, 124 (S.D.N.Y. 2003) (finding the operator of a website that sold counterfeit Tiffany jewelry liable for willful infringement).
17 *See* Tiffany (NJ), LLC v. 925LY.Com, No. 2:11-CV-00590-LDG-GWF, 2011 WL 2118634 (D. Nev. May 25, 2011) (issuing a preliminary injunction in favor of Tiffany).
18 *See* Two Pesos, Inc. v. Taco Cabana, Inc., 505 U.S. 763, 774 (1992).

The Failed Trans-Pacific Partnership: What It Might Have Meant To Biotech and Pharma

By Kevin E. Noonan

The Trans-Pacific Partnership (TPP) was the latest in a series of multination international agreements aimed at reducing trade barriers and promoting global free trade. Most of these agreements are "regional," like the North American Free Trade Agreement (NAFTA) between the United States, Canada, and Mexico, but others have global scope (e.g., the GATT/TRIPS agreements that created the World Trade Organization (WTO)). The TPP's goals were lofty, to "promote economic growth; support the creation and retention of jobs; enhance innovation, productivity and competitiveness; raise living standards; reduce poverty in our countries; and promote transparency, good governance, and enhanced labor and environmental protections" according to the U.S. Trade Representative.[1] However, the subject matter scope of this agreement and the secrecy with which it was negotiated have engendered deep suspicions from a variety of groups regarding whether its goal is truly free trade or whether there are more nefarious motivations behind it. And with the election of Donald Trump, these efforts have apparently amounted to nothing.

The TPP was negotiated over the past seven years and was signed on February 4, 2016, in Auckland, New Zealand, by 12 nations: Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, United States, and Vietnam. Its principal provisions (set out in 30 chapters) included lowering tariffs and other trade barriers, providing a mechanism for disputes between investors and member states, and a variety of harmonization provisions to intellectual property (IP) law. These IP provisions have been the source of much of the political opposition to the TPP. And while some (or all) of the other nations may sign the treaty (and if enough of them do so it will come into force in those countries), the U.S. probably will not. Because of these possibilities, the provisions of the treaty remain relevant and could form the basis for an international agreement the U.S. could agree to in the future.

IP Provisions

The IP provisions of the TPP have broad scope, encompassing copyrights, trademarks, patents, and trade secrets. These provisions are aimed at establishing a minimum level of protection among the member states, and to harmonizing such protections where possible. The express aims of these sections of the TPP are to "contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."[2] The TPP expressly contains provisions permitting signatories to "adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development,"[3] similar to the amendments adopted by the WTO under the Doha Declaration.[4] The TPP also gives signatories the right to adapt their laws to "prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology" (presumably as judged by each country).[5] Each signatory must affirm that it has ratified[6] or will ratify[7] several prior international agreements.[8]

Other general provisions require equal treatment of citizens of other signatory states and signatory state nationals;[9] transparency (e.g., regarding Internet availability of a signatory's IP laws and regulations);[10] and cooperation between member states with regard to intellectual property,[11] in particular protection of "traditional knowledge."[12]

Trademarks

Regarding trademarks, the TPP requires that collective marks, certification marks, sounds, geographical indications, and (to the extent possible) scents must be capable of registration.[13] Trademark exclusivity that precludes another using a mark that would raise a likelihood of confusion is recognized,[14] but so is fair use that "take[s] account of the legitimate interest of the owner . . . and of third parties"[15] as well as provisions for "well-known" marks.[16] The TPP also specifies "procedural aspects" of trademark examination, opposition, and cancellation proceedings.[17] As part of the harmonization aspects of the TPP, it requires an initial term and each renewal of a mark to last 10 years.[18] With respect to Internet domain names, the TPP requires procedures for settling disputes according to principles approved by ICANN.[19] Finally, several subsections relate to country names and geographical indications used as trademarks,[20] which are directed at protectionist practices purportedly used by some countries to discriminate against products not of local origin.

Patents

The patent provisions[21] define eligible subject matter broadly, for "any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step and is capable of industrial application."[22] However, signatory countries are also permitted to exclude from patent eligibility "diagnostic, therapeutic and surgical methods for the treatment of humans or animals," and "animals other than microorganisms, and essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes" (thus, there is no respite to be garnered from the TPP from the current patent ineligibility regime in the United States).[23] The TPP (somewhat surprisingly) contains a 12-month "grace period"[24] patterned after § 102 of the America Invents Act[25] under a "first inventor to file"-styled regime.[26] Transparency is the express basis for provisions regarding patent application publication and public accessibility to the file wrapper,[27] and there are also provisions for patent term adjustment due to "unreasonable" delays in issuing a patent (defined as being longer than five years).[28] The TPP permits signatories to restore portions of patent term expended by regulatory review (due to "unreasonable curtailment"),[29] similar to patent term extension provisions of U.S. law, and to protect industrial designs.[30]

Exclusivity provisions regarding agricultural chemicals and, more urgently, pharmaceuticals and biologic drugs have engendered the most controversy and opposition. Agricultural products regulated prior to marketing receive at least 10 years market exclusivity under the TPP.[31] Regulated pharmaceutical products are entitled to at least five years of market exclusivity (subject to the provisions of the Doha Declaration),[32] and signatories must provide a legal framework for the pharmaceutical license holder to challenge approval and marketing of any generic version of a patented drug.[33] Biologic drugs are afforded at least eight years of market exclusivity, or at least five years combined with other regulations in a signatory country that result in at least eight years of exclusivity.[34] All these provisions are subject to further review by the signatories after 10 years, to provide the ability to adapt the exclusivity term based on experience. The exact phrasing of these terms is important to understanding their scope. Particular measures relating to pharmaceutical products can be found in TPP Articles 18.50–18.54.[35]

Because even these exclusivity terms—which are shorter than those available to biologic drug innovators in the United States (12 years) or Europe (10 years)—are longer than the terms (i.e., no exclusivity term) available in many of the signatory states, their inclusion in the TPP has produced opposition from nongovernmental organizations. In particular, organizations such as Doctors without Borders,[36] Public Citizen,[37] and others have opposed the exclusivity terms on the grounds that pharmaceutical corporate interests have been satisfied at the expense of public access to medicine, particularly in developing country signatories of the TPP.

Copyrights

The copyright provisions[38] of the TPP have also caused controversy, particularly from groups like the Electronic Frontier Foundation that oppose copyright restrictions in almost any form.[39] The basic term is set at not less than the life of the author plus 70 years;[40] exceptions include "legitimate purposes such as, but not limited to: criticism; comment; news reporting; teaching, scholarship, research, and other similar purposes; and facilitating access to published works for persons who are blind, visually impaired or otherwise print disabled."[41] The TPP provides penalties not only for unauthorized reproduction but also for "circumvention of effective technological measures that authors, performers, and producers of phonograms use in connection with the exercise of their rights and that restrict unauthorized acts," including criminal penalties (albeit ones that exempt "a non-profit library, museum, archive, educational institution, or public non-commercial broadcasting entity").[42] Similar remedies are included for violation of "rights management information."[43]

IP Enforcement

The TPP also contains enforcement provisions for protecting IP rights, aimed at "permit[ting] effective action against any act of infringement of intellectual property rights covered by this Chapter, including expeditious remedies to prevent infringements and remedies that constitute a deterrent to future infringements," available in equal measure for patent, copyright, or trademark infringement.[44] In addition to damages and the possibility of an injunction against future infringement, the TPP empowers signatories to destroy infringing articles, particularly counterfeit goods,[45] and there are particular provisions relating to counterfeit articles identified at a signatory's borders.[46]

Also of note is that the TPP provides, for the first time in an international trade agreement, criminal penalties for trade secret theft.[47]

Contained in the criminal enforcement provisions for willful trademark or copyright infringement are penalties for counterfeiting[48] and for intercepting or transmitting without authorization an encrypted program-carrying cable signal,[49] and provisions relating to Internet service providers with regard to preventing unauthorized use of copyrighted materials.[50]

Other TPP Features

Regarding specifics of the other important provisions of the agreement, the TPP is estimated to have reduced or eliminated immediately upon ratification about 18,000 tariffs, including those on all U.S. manufactured goods and almost all U.S. farm products. These provisions were intended to benefit the United States as an exporter, where for example high tariffs on American automobiles and other products have keep those items out of foreign markets to the country's detriment. The "investor-state dispute settlement" provisions provide a path for an individual or private company to sue a foreign government, which is prohibited under international law absent such an agreement.[51] While this would permit a company to have legal recourse through arbitration to protest unfair treatment, fears have been raised that it could be used by multinational companies to challenge environmental protection and labor laws. Tobacco was expressly excluded from the scope of these provisions due to fears the tobacco companies would do just that and bring actions against laws in member states restricting tobacco use (such as those in the United States).

According to the U.S. Trade Representative, the TPP would have benefited the United States by opening foreign markets while protecting the "nearly 40 million American jobs [that] were estimated to be directly or indirectly attributable to 'IP-intensive' industries in 2012."[52] The signatory countries (and perhaps other countries in the region that have evinced an interest in becoming signatories in the future, such as Korea and China) are a growing part of the globe and are expected to comprise the world's fastest growing market over the next 10–20 years for "film, medicines, and new digital products for consumers, [and] civil aircraft and satellites."[53] These opportunities are balanced by the challenges of piracy, cyber theft, and counterfeiting, all issues that the TPP was intended to address.

TPP Ratification

The agreement cannot come into effect unless it is ratified, either by all 12 nations or by enough of them to constitute 85 percent of their combined gross domestic product (GDP) (these nations comprise about 40 percent of global GDP). In the United States, President Obama was able to get so-called "fast track" ratification authority, wherein Congress must bring the treaty to a vote within 90 days of the treaty being formally sent to Congress for ratification, and there can be no amendments, under the Bipartisan Congressional Trade Priorities and Accountability Act of 2015, which was passed on June 24, 2015, and signed into law on June 29, 2015.[54] Nevertheless,

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a significant number of disparate groups exerted sufficient political pressure against ratification to have delayed a vote until the lame duck session of Congress that convenes after the election.

Even if ratified, the effects on U.S. law would be minimal (although it could intensify pressure for a reduction in the term of biosimilar exclusivity, which President Obama has been trying to reduce from twelve years to seven ever since the biosimilar law[55] was passed). The largest benefits to U.S. industry would be in redressing apparent discrimination against American goods in certain of the signatory countries, such as those chronicled each year in the U.S. Trade Representative's Special 301 Report.[56] But no matter what the actual advantages might have been to the TPP for the U.S., Mr. Trump's election has all but doomed any chance Congress will ratify the TPP (and President Obama has conceded as much). The real question is whether treaties such as the TPP are still politically feasible or whether the Trump administration will succeed in having America withdraw from such agreements no matter what the consequences for American global trading interests.

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Endnotes

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5 TPP, *supra* note 2, at art. 18.3.2.
6 Specifically, the Patent Cooperation Treaty, the Paris Convention, and the Berne Convention.
7 Specifically, the Madrid Protocol, the Budapest Treaty, the Singapore Treaty, the International Convention for the Protection of New Varieties of Plants, the WIPO Copyright Treaty, and the WIPO Performances and Phonograms Treaty.
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10 *Id.* at art. 18.9.
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12 *Id.* at art. 18.16.
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19 *Id.* at art. 18.28.
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30 *Id.* at arts. 18.55–18.56.
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32 *Id.* at art. 18.50.
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36 *See Help Us Fix the TPP!,* Doctors without Borders, http://www.doctorswithoutborders.org/help-us-fix-tpp (last visited May 1, 2016).
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McDonnell Boehnen Hulbert & Berghoff LLP is pleased to announce firm partners Paul H. Berghoff, Daniel A. Boehnen, Grantland G. Drutchas, Bradley J. Hulbert, Kevin E. Noonan, Ph.D., Matthew J. Sampson, Leif R. Sigmond, Jr. and Donald L. Zuhn, Jr., Ph.D. were selected by their peers for inclusion in the *Best Lawyers in America*® 2017 edition. Of these attorneys, Mr. Berghoff and Dr. Noonan were also named "Lawyer of the Year" respectively for Litigation—Intellectual Property (Chicago) and Biotechnology Law (Chicago). *Best Lawyers* is a highly respected peer-review publication that is widely regarded by both clients and legal professionals as a significant honor.

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