



The IP Beacon[®] The Intellectual Property Law Newsletter of Haynes and Boone, LLP

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The USPTO Extends Certain Trademark Deadlines Through April

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As first announced in March, the USPTO has provided two avenues for relief to trademark owners impacted by the novel coronavirus (COVID-19) pandemic. These policies have recently been updated and extended through May:

1. CARES Act Relief: Applicants and registrants can claim the benefit of a *grace period* extension on many types of filings with deadlines between, and inclusive of, March 27, 2020 and May 31, 2020.¹ The requesting party must make the late filing or payment by Monday, June 1st with a statement that COVID-19 *materially interfered* with meeting the original deadline. This alert mostly will elaborate on this grace period measure.
2. Other Relief - Petitions: The USPTO will waive its fees for both Petitions to Revive applications abandoned by May 31, 2020 and Petitions to the Director to reinstate registrations that were cancelled or expired within this timeframe.²

We recommend trying to meet all trademark deadlines during this time – yet turning to the options explained here if applicable and necessary in your situation. Even if you need not make use of these extension or petition options, these developments may have an impact on your trademark decisions and portfolio, which we discuss further below.

Cares Act Relief

What filings may benefit from a grace period?

The notice applies to an expansive list of trademark filings:

- Priority filings (i.e., filing in the U.S. with a claim of priority date from a foreign application);
- Transformations of extensions of protection (from an International Registration to a U.S. application);
- Statements of Use and Requests for Extension of Time to File Statements of Use;
- Office Action Responses;³
- Notices of Appeal from a Final Office Action;
- Section 8 Affidavits of Use or Excusable Nonuse; and
- Renewals.

As for *inter partes* TTAB filings, the notice only applies to Notices of Opposition and Requests for Extension of Time to Oppose.

Unlike several foreign jurisdictions that have implemented blanket extension policies or shut down trademark operations, the USPTO does not provide for automatic granting of extensions or suspend any current due dates. The U.S. grace period is only available to applicants, registrants, trademark practitioners, or other individuals who assert that the outbreak materially interfered with a timely filing or payment.

How do you request relief?

To receive the benefit of additional time, those impacted must make the late filing or payment by *Monday, June 1st*⁴ and include a statement in the filing that the COVID-19 outbreak caused a material interference leading to the delay.

What qualifies as a material interference?

The USPTO has indicated that at least the following may qualify as a material interference: office closures, cash flow interruptions, lack of access to files or other materials, travel delays, or personal or family illness.

We therefore expect that extensions would be available where, e.g., an applicant cannot obtain a proper specimen image due to a shelter-in-place order, a business makes significant cuts to expenditures and staff, or a business (or its trademark counsel) is otherwise particularly strained due to an inability to fully operate under local or state ordinances.

We do not know how closely the justifications for each delay will be reviewed. In many situations, including less clear ones, the best course of action could be to meet the original deadline. If the pandemic has impacted your trademark budget or your ability to otherwise meet a trademark deadline between, and inclusive of, March 27th and May 31st, we recommend that you contact your trademark counsel for review.

Other Relief - Petitions

The USPTO is waiving the petition fee to revive trademark applications or reinstate registrations that became abandoned, canceled, or expired by May 31, 2020.

The petitioner must explain how the missed deadline “was due to the COVID-19 outbreak.” This is the same “material interference” standard as required for obtaining an extension for certain other trademark filings discussed above. The USPTO has not indicated whether it will be more lenient in granting petitions, though, as compared to petitions pointing to other factors. The petition deadline has not changed; a petition is due two months from notice of abandonment or cancellation, or six months from online USPTO records reflecting the abandonment or cancellation records if the USPTO’s notice was not received.

What else should brand owners think about?

- The extension policy, and ability to file petitions without filing fee, has potential impact on issues beyond your own upcoming deadlines:
- Trademark Clearance - In the coming weeks, one should not assume that a third party’s recently missed deadline necessarily will cause its application or registration to lapse. (Yet, note that the deadline for petitions, including Petitions to Revive, is not protected under the USPTO’s notice.)
- Potential Oppositions - The USPTO’s notice effectively extends all opposition windows slated to close between March 27th and May 31st. Do not assume that published applications have avoided a notice of opposition or an extension to oppose until at least several weeks after the original deadline has passed.
- Priority Filings - Foreign applications filed as long ago as September 27, 2019, could enable a competitor to jump ahead of your pending application for a confusingly similar mark.

Could things change again?

Yes. The CARES Act has granted temporary authority to Director Iancu to modify USPTO deadlines for up to 30 days after the national emergency declaration terminates, which has yet to occur as of this publication. As a result, the USPTO may very well issue additional notices extending or otherwise modifying trademark deadlines in the coming months.

¹ The Coronavirus Aid, Relief, and Economic Security Act (CARES Act), at Section 12004, granted USPTO Director Andrei Iancu temporary authority to modify the USPTO’s statutory deadlines. In response, Director Iancu issued a notice on March 31st that initially set forth a 30-day grace period exception for certain deadlines through April 30th. Director Iancu issued a new notice on April 28th extending the same deadlines again

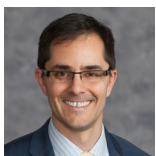
² This was first announced via a USPTO notice dated March 16th, which declared that the Office considers the effects of coronavirus to be an “extraordinary situation” that justifies the waiving of petition fees for trademark applicants and owners (and certain patent customers). The USPTO’s April 28th notice further clarified and extended this relief option.

³ This presumably includes Requests for Reconsideration, i.e., Responses to Final Office Actions. That especially seems to be the case, as Notices of Appeal from a Final Office Action are also covered by this notice.

⁴ May 31st is a Sunday. As a result, the final date to file and take advantage of the extension is moved to Monday, June 1st.

Alexander Lutzky in IP Litigator: Practice Areas: Patent Litigation

Alexander Lutzky



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Did the Federal Circuit Just Raise the Evidentiary Bar for Establishing Obviousness?

According to the panel in *OSI Pharmaceuticals, LLC v. Apotex, Inc.*, Slip Op. No. 2018-1925 (Fed. Cir. Oct. 4, 2019), the answer to the question

posed in this article’s title is a solid no. Considering the opinion’s precedential nature and the facts in the case, the Federal Circuit, however, may have just given patentees extra ammunition to defeat an obviousness challenge on evidentiary grounds.

The Federal Circuit analyzed whether certain pharmaceutical method claims related to a treatment for lung cancer were obvious and concluded that the lack of efficacy data in asserted prior art showed a person of ordinary skill would not have a reasonable expectation of success in applying their teachings. This holding reversed an obviousness determination by the PTAB in a preceding IPR of the patent at issue, and shows that for challengers mounting an obviousness challenge, prior art containing data-based evidence may be needed to be successful, particularly if the patent being targeted is in the pharmaceutical or chemical arts.

Technical and Procedural Background

Patentee OSI Pharmaceuticals, LLC (OSI) owns U.S. Patent 6,900,221 (the ‘221 patent), which it filed in November of 2000. Claims 44-46 and 53 of the ‘221 patent are directed to methods of treating Non-Small Cell Lung Cancer (NSCLC) with a chemical compound known as “erlotinib.”¹ By the end of the late 1990’s, NSCLC was the leading cause of cancer deaths in the U.S., and existing therapies, particularly chemotherapy, were inadequate.² Throughout this period, investigators pursued numerous studies examining different ways to inhibit the epidermal growth factor receptor (EGFR) in cancers. These studies included examining the efficacy of erlotinib to treat a variety of cancers, including NSCLC. After an extended period of prosecution, the ‘221 patent issued in May of 2005. In 2015, OSI filed suit against Apotex, alleging infringement of the ‘221 patent.³ Apotex responded with an IPR, asserting claims 44-46 and 53 were invalid as being obvious over U.S. Patent 5,747,498 to Schnur in view of either an article by Gibbs printed in early 2000 or an annual SEC-required 10-K Form filed by OSI in 1998. The PTAB instituted the IPR and found that “a person of ordinary skill would have combined Gibbs or [the] OSI 10-K with Schnur and had a reasonable expectation of success in achieving the invention” disclosed in the claims, and that “Schnur disclose[d] all of the limitations of claims 44 and 53 except the treatment of NSCLC.”⁴ OSI appealed the obviousness decision to the Federal Circuit, and also challenged the constitutionality of the IPR process. The panel disposed of the constitutionality issue by citation to several recent decisions, and that aspect of the opinion will not be discussed here.

The Asserted Prior Art Discloses the Use of *erlotinib* to Treat Lung Cancer

There was no dispute among the parties that the asserted prior art was available to the public before the date of invention of the asserted claims, which was March 30, 2000.⁵ Therefore, the main issue for the Federal Circuit to decide was whether the combination of Schnur and Gibbs or Schnur and OSI's 10-K sufficiently disclosed the use of *erlotinib* to treat NSCLC such that a person of ordinary skill would have a reasonable expectation of success. Schnur disclosed a variety of chemical compounds useful for treatment of diseases "such as cancers, in mammals." The patent listed *erlotinib* as "a preferred compound, and [a] method for synthesizing *erlotinib* is described."⁶ It also stated the compounds were "potent inhibitors" of EGFR and that the compounds are "therapeutics 'for the treatment of a variety of human tumors (renal, liver, kidney, bladder, breast, gastric, ovarian, colo-rectal, prostate, pancreatic, lung, vulval, thyroid, hepatic carcinomas, sarcomas, glioblastomas, various head and neck tumors) . . .'"⁷ The Gibbs article summarized a series of published research studies, including a study that referred to erlotinib being in clinical trials to treat cancer. In reviewing the status of the clinical trials, Gibbs asserted that "these compounds appear to have good anti-cancer activity in preclinical models . . . particularly in patients with *non-small cell lung cancer*."⁸ Finally, the OSI 10-K plainly stated:

"[erlotinib] which targets a variety of cancers including ovarian, pancreatic, *non-small cell lung* and head and neck, achieved a significant milestone with the completion of Phase I safety trials and the initiation of Phase II clinical trials in the United States in cancer patients. [Erlotinib] is a potent, selective and orally active inhibitor of the epidermal growth factor receptor, a key oncogene in these cancers."⁹

The Federal Circuit Finds a Lack of Substantial Evidence to Support Obviousness

Despite the foregoing, the Federal Circuit panel determined that "properly read, these combinations do not provide substantial evidence supporting the Board's findings of reasonable expectation of success."¹⁰

Two facts colored the panel's analysis. First, the opinion emphasized the lengthy process and time frame needed for a drug to proceed from conception to FDA approval.¹¹ The process includes filing an Investigational New Drug application following preclinical studies, followed by Phase I, Phase II, and finally, Phase III studies that conclude with the filing of a New Drug application to the FDA.¹² Second, the panel observed evidence in the record showing that 95% of therapies to treat NSCLC never made it out of Phase II and on to FDA approval. Viewing the record through the foregoing lens, the opinion criticized the examination of the Gibbs article by the PTAB. Digging into the substance behind the disclosure that *erlotinib* "appear[s] to have good anti-cancer activity," the panel found that the underlying study cited to support that statement did not test erlotinib in treating NSCLC, and they noted that Apotex's expert agreed.¹³ Based on these findings, the panel essentially disqualified the relevance of Gibbs in the obviousness analysis.

More critically, the opinion appears to hinge on its view that the asserted prior art references "contain *no data or other promising information* regarding *erlotinib*'s efficacy in treating NSCLC."¹⁴ In the panel's view, the high failure rate of NSCLC drugs in Phase II coupled with the lack of "efficacy data or any other reliable indicator of success" showed that "the only reasonable expectation at the time of the invention was failure, not success."¹⁵ Thus the Federal Circuit reversed the PTAB and held the claims at issue to be non-obvious.

The Efficacy of the Federal Circuit's Analysis

Close scrutiny of the panel's analysis demonstrates the questionable value of this precedential decision. The Federal Circuit's central thesis is that, because of the high failure rate of *erlotinib* targeting NSCLC in Phase II trials and the lack of efficacy data, there was no reasonable expectation of success.¹⁶ In addition to dismissing the Gibbs reference, the panel similarly dismisses the *patentee*'s very own 10-K because it lacked any data.¹⁷ As a result, the Federal Circuit rejected Apotex's argument that the combination of Schnur, which discloses the use of *erlotinib* as a therapy against lung cancers, with OSI's 10-K supported an obviousness determination. In doing so, the panel seems to disregard its own precedent. In *Allergan, Inc. v. Sandoz, Inc.*, the Federal Circuit

cautioned “that [while] formulation science carries with it a degree of unpredictability, ‘obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success.’”¹⁸ What qualifies as “a reasonable probability” will be dependent on the field of art, yet the decision is silent on this point. Expert testimony from both parties acknowledged the high failure rate during drug development,¹⁹ establishing that high failure rate in drug development is presumably “reasonable.” Furthermore, in its 10-K that is to be relied on by investors, the patentee stated that “[erlotinib,] which targets . . . *non-small cell lung* [cancer], achieved a significant milestone with the completion of Phase I safety trials and the initiation of Phase II clinical trials in the United States in cancer patients.”²⁰ As such, the patentee arguably believed there was a reasonable probability of success that erlotinib would be an effective therapy against NSCLC. Otherwise, it would not have entered Phase II. Thus, it could be argued that a person of ordinary skill at the time of the invention would have recognized that the teachings of Schnur could be applied to treat NSCLC as described in the claimed invention with a reasonable probability of success. Yet, the panel concluded that “a fact finder could not reasonably find that the 10-K statement combined with Schnur would have been sufficient to create a reasonable expectation of success.”

Conclusions

The panel’s silence on what qualifies as a “reasonable” expectation or probability of success in this case may leave the reader questioning the result. Despite the panel’s express limitation that “we do not hold today that efficacy data is always required for a reasonable expectation of success,”²¹ the curious designation of the opinion as precedential means that practitioners should consider keeping this decision on the shelf when litigating obviousness in fields that require extensive data to support product development and commercialization.

¹Slip op. at 4, 5. Claim 44 is an independent claim with claims 45-46 and 53 being dependent.

²Slip op. at 2.

³*OSI Pharm., LLC v. Apotex, Inc.*, No. DED0115-cv-0772, Complaint (D.Del. Sept. 2, 2015).

⁴Slip op. at 9-10.

⁵Slip op. at 5.

⁶Slip op. at 6.

⁷*Id.* (emphasis added).

⁸*Id.* at 7 (emphasis added).

⁹*Id.* at 8-9 (emphasis added).

¹⁰*Id.* at 15.

¹¹*Id.* at 3, 16.

¹²*Id.* at 3-4.

¹³*Id.* at 14-15.

¹⁴*Id.* at 16 (emphasis added).

¹⁵*Id.* at 18.

¹⁶*Id.*

¹⁷*Id.* at 17.

¹⁸*Allergan, Inc. v. Sandoz, Inc.*, 726 F.3d 1286, 1929 (Fed. Cir. 2013) (quoting *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007)).

¹⁹Slip op. at 16, 17.

²⁰*Id.* at 8-9 (emphasis added).

²¹*Id.* at 18.

Joseph Lawlor in Mobile Marketing Magazine: Running a Micro-Influencer Campaign

Joseph Lawlor



Joseph Lawlor

The Michael Bloomberg 2020 presidential campaign has hired hundreds of individuals in California to post social media content supportive of the New York billionaire, as first reported by the [Wall Street Journal](#). This strategy is an unorthodox method for distributing sponsored content at a scale previously unheard of.

Bloomberg’s strategy has already hit several roadblocks. Its quality control team has failed to prevent paid micro-influencers from making false postings on social media. 70 Bloomberg micro-influencers have been [banned by Twitter outright](#). Brands will be wise to consider the significant compliance and PR costs before engaging in a micro-influencer campaign of this scale.

Brands are increasing their influencer marketing budgets at a swift pace, but they should be wary of engaging in a Bloomberg campaign-style social media campaign that relies on hundreds of micro-influencers. A lengthy brand activation utilizing micro-influencers may promise sales and engagement KPIs that excite a brand’s marketing team. However, running a months-long campaign that requires managing hundreds

of micro-influencers posting both pre-written and unique content daily across several platforms requires a massive and expensive compliance program. A Bloomberg-style activation will rarely be a cost-effective use of a brand's marketing dollars.

Brand guidelines

The prototypical influencer marketing campaign involves a brand that engages one, or a handful, of well-known influencers who typically each have more than 100,000 followers. Either the brand team or an outside agency ensures that the influencer's posts meet brand guidelines and comply with relevant law. Brands also regularly engage micro-influencers, who typically have between 1,000 and 100,000 followers. Micro-influencers are generally engaged for brand activations that are aimed at niche markets where the influencer has a reputation that outpaces their follower count.

According to a 2019 Rakuten Marketing report, micro-influencers make up 36 per cent of global brand partnerships, compared to 30 per cent for high-tier celebrity influencers. Importantly, recent studies have shown that the engagement rate for micro-influencers can be 1.5-4x the rate for celebrity influencers.

The higher engagement rate of micro-influencers comes with the trade-off of significantly smaller follower counts. While a celebrity with 1m Instagram followers may only generate a 2 per cent engagement rate compared to a micro-influencer at 4 per cent, the celebrity influencer is generating much greater numbers of raw comments, likes, and shares.

The Bloomberg 2020 micro-influencer strategy represents a very public rollout of a new frontier in micro-influencer marketing. The Bloomberg team is hiring hundreds of micro-influencers in California, who tend to have no notable public reputation. Instead, the Bloomberg campaign is seeking out individuals with pedestrian online presences.

There may be some benefit to paying \$2,500 a month to hundreds of individuals in a political campaign where the appearance of authentic grassroots support can lead to gains at the polls. This article does not

address the legality of the Bloomberg campaign, which involves evaluating FEC regulations and social media Terms of Service that do not apply to typical brand-focused influencer activations.

Costs of compliance

Any brand that may consider hiring an army of micro-influencers should seriously consider the costs of compliance and their ability to oversee hundreds of inexperienced micro-influencers. It will be difficult for a brand to control two critical components of such a campaign in a cost-effective manner: proper disclosure and truth in advertising.

If an individual receives anything of value in return for posting social media content about a brand, the post must include a prominent disclosure alerting all viewers that it is advertising content. Disclosure rules on most social media platforms can be accomplished by placing "#ad" prominently in the posting.

However, disclosure in a Bloomberg-style campaign can be tricky for a few reasons. Inexperienced micro-influencers, like the individuals being paid by Bloomberg's campaign, are unlikely to be familiar with the Federal Trade Commission rules regulating influencer marketing. An inexperienced user engaging in his or her first ever paid marketing campaign could easily forget to add "#ad" to their posts or even use terms like "spon" or "collab" that are generally disfavored.

According to the WSJ, the Bloomberg campaign is not advising its micro-influencers to disclose that their posts are advertising, and instead describes their effort as "a new form of political advertising rather than paid influencer content." The campaign's approach to disclosures has already led to the type of negative market reaction savvy brands scrupulously avoid.

Jerry Media

The Bloomberg campaign came under fire just last week, following a series of social media posts by Jerry Media that were revealed to be paid advertising for the Bloomberg 2020 campaign. These ads were intended to look like private DMs from the Bloomberg campaign

to marketing firm Jerry Media asking the company to create a meme for Bloomberg that would rival the popular Bernie Sanders 'Asking for Your Support' meme.

While, these posts carried a tag that said, "Yes this is really sponsored by @mikebloomberg," the entirety of the ad left it unclear whether it was simply a meta-meme or actual advertising. The fact that the ad carried such a long disclosure rather than the ubiquitous "#ad" only served to highlight this potential confusion. Ultimately, news outlets clarified that the Bloomberg campaign had in fact paid Jerry Media to run the ads.

In addition to ensuring that its micro-influencers provide proper disclosures, a brand also must work to ensure that its advertising is true. Contrary to some public misconception, an influencer who endorses a brand must actually use the product and only make truthful statements regarding the product. Thus, for example, it would be inappropriate for a paid micro-influencer to post to his or her social media that: "I will be voting for Mike Bloomberg in the 2020 Democratic Primary" if he is planning to vote for one of the other candidates. Similarly, a brand influencer cannot discuss experience with a product that they have not used or provide an endorsement of qualities of a product that is inconsistent with their honest opinions.

Generally, when a brand employs an influencer, the brand tracks the influencer's social media postings for compliance (or engages an outside agency or law firm to do so) and sometimes provides the influencer with pre-written content to post. There will often be a discussion regarding the content of posts to ensure that they match the brand's guidelines and the influencer's honest opinions about the product.

Untenable tension

Running a large-scale micro-influencer campaign can create an untenable tension between the brand's desire to provide pre-written content that meets its guidelines, and the requirement that all postings accurately state the influencer's opinions and experience. Most brands will simply not have the

bandwidth, nor will it be cost effective, to engage in detailed conversations with these micro-influencers to tweak pre-written content to match the influencer's opinions. Thus, micro-influencers will either post pre-written content that, in some cases, will not be true, or will post content in their own words that does not meet the brand's guidelines.

The Bloomberg campaign's efforts highlight the difficulty in ensuring that micro-influencer advertising is truthful. According to the WSJ, Bloomberg's approach will be to "suggest content for sharing and exert some control over the social-media outreach efforts." The Bloomberg team will also have a "quality-control staff [to] verify that the organizers are posting appropriately."

Bloomberg's micro-influencers have routinely been reposting the stock text and links provided by the Bloomberg campaign according to the LA Times. While this practice may ensure compliance with brand guidelines, it does not encourage truthfulness. According to the LA Times, Bloomberg's army of micro-influencers include "A vocal Bernie Sanders supporter. A Chicagoan with zero followers on Twitter. A dozen registered Republicans."

The LA Times also detailed the postings of one Bloomberg influencer who, after sending a paid message supportive of the candidate, quickly followed up with another message, "Please disregard, vote Bernie or Warren."

Quality control

Bloomberg's quality control team is clearly unable to keep up with the demands required to ensure compliance by its army of posters. More broadly, it does not seem practical, or an efficient use of a brand's resources, to employ the sort of detailed quality-control that would be necessary to run an appropriate micro-influencer campaign at this scale that complies with the relevant regulations.

In a campaign with hundreds of micro-influencers, the failure to ensure proper disclosure and truthful advertising in even a small percentage of cases could

be significant enough to earn the attention of the FTC in the US, and the equivalent regulator for campaigns in other countries. Thus, quality control would require a significant investment. The primary difficulty a brand would encounter running a Bloomberg-style micro-influencer campaign is that the compliance costs would more than likely dwarf the returns as measured by the brand's KPIs.

It is possible to foresee a Bloomberg-style campaign working for a brand where the activation is limited in time and scope, such as a single post by each micro-influencer in order to get a brand trending. However, a full-fledged, months-long social media campaign of this type would require a significant investment in compliance resources to avoid FTC scrutiny and related public relations backlash.

Michael Tobin: 'Consisting Essentially of' Claims Nixed at Federal Circuit

Michael Tobin



Michael Tobin

In *HZNP Medicines LLC v. Actavis Laboratories UT, Inc.*,¹ the U.S. Court of Appeals for the Federal Circuit affirmed the district court's holding that the transitional phrase "consisting essentially of" was indefinite as used in several claims of patents owned by HZNP Medicines LLC and Horizon Pharma USA, Inc. ("Horizon").²

Background

Horizon's patents cover its PENNSAID 2% product, which is a non-steroidal anti-inflammatory drug ("NSAID") and the first FDA-approved twice-daily topical diclofenac sodium formulation for the treatment of pain of osteoarthritis of the knees. Claim 49 of U.S. Patent No. 8,252,838 (the "'838 patent") is illustrative of Horizon's formulation patents and recites:

A topical formulation consisting essentially of:

- 1-2% w/w diclofenac sodium;*
- 40-50% w/w DMSO;*
- 23-29% w/w ethanol;*
- 10-12% w/w propylene glycol;*
- hydroxypropyl cellulose; and*
- water to make 100% w/w, wherein the topical formulation*
- has a viscosity of 500-5000 centipoise.*

Prior to the appeal to the Federal Circuit, the district court found that the phrase "consisting essentially of" in claim 49 of the '838 patent was indefinite. The district court noted that, under *PPG Indus. v. Guardian Indus. Corp.*,³ "consisting essentially of" limits a claim to the recited ingredients and any unlisted ingredients that would not materially affect the basic and novel properties of the invention.

The district court then determined that the basic and novel properties included:

- (1) Better drying time;
- (2) Higher viscosity;
- (3) Increased transdermal flux;
- (4) Greater pharmacokinetic absorption; and
- (5) Favorable stability.

With respect to the "better drying time," the district court found that two different methods were taught for evaluating the drying time, and those methods provided disparate results, with some of the formulations according to the claimed invention meeting the "better drying time" characteristic in one method but not the other. Based on the inconsistencies between the results from the two methods, the district court found that a person of ordinary skill in the art ("POSITA") would not have had "reasonable certainty"⁴ regarding the scope of the basic and novel properties of the invention.

The Federal Circuit’s Decision

On appeal to the Federal Circuit, the majority of the three-judge panel affirmed the district court’s determination regarding the indefiniteness of “consisting essentially of.” First, the majority agreed that the five properties recognized by the district court are the basic and novel properties of Horizon’s patents, with each one being highlighted in the specifications by subheadings. The majority further “determined that the basic and novel properties of an invention are part of the scope of the claims in this case.”⁵ In support of this finding, the court discussed prior “consisting essentially of” cases,⁶ and asserted that “the crucial teachings from both *PPG Industries* and *AK Steel* is that courts evaluating claims that use the phrase ‘consisting essentially of’ may ascertain the basic and novel properties of the invention at the claim construction stage, and then consider if the intrinsic evidence establishes what constitutes a material alteration of those properties.”⁷

On appeal to the Federal Circuit, the majority of the three-judge panel affirmed the district court’s determination regarding the indefiniteness of “consisting essentially of.”

Regarding the “better drying time” property, the majority held that “the district court did not err in its determination that a POSITA would not know under what standard to evaluate the drying rate of the invention, thus rendering the basic and novel property of ‘better drying rate’ indefinite.”⁸ Consequently, Horizon’s “consisting essentially of” claims were affirmed as indefinite. Although the majority assures that “the phrase ‘consisting essentially of’ is not per se indefinite,”

the opinion creates vulnerabilities for claims using this transitional phrase. For instance, even though Horizon’s patents described five basic and novel characteristics, both the district court and Federal Circuit focused on a single property, the indefiniteness of which was sufficient to invalidate the entire claim. In light of this decision, applicants and practitioners may reconsider using “consisting essentially of,” as doing so will presumably place large swaths of the specification under definiteness review.

The Dissent

In his dissent, Judge Newman alludes to a potentially safer route for defining claim scope equivalent to “consisting essentially of” by contending that the majority’s holding implies “that the ‘consisting essentially of’ claims are invalid for indefiniteness unless the claims include the ‘basic and novel properties’ of the composition and how these properties are measured.”⁹ Although Judge Newman contends that “[t]his new rule is not in conformity with precedent,” practitioners deferring to the alleged new rule might draft a claim using “comprising” and including one or more basic and novel properties and the mode of measuring the same. Such a claim would require the listed ingredients and would exclude any unlisted ingredients yielding a formulation not having the recited properties, and thus would be substantially similar in scope to a “consisting essentially of” claim not reciting those properties while avoiding some of the uncertainties surrounding “consisting essentially of” that are highlighted in this case.

For owners and assignees of patents including “consisting essentially of” in their claims, Judge Newman warns that “[t]his new rule of claiming compositions casts countless patents into uncertainty.”

For owners and assignees of patents including “consisting essentially of” in their claims, Judge Newman warns that “[t]his new rule of claiming compositions casts countless patents into uncertainty.”¹⁰ However, while this is a precedential opinion, the majority attempts to limit its reach by stating:

To be clear, we do not hold today that so long as there is any ambiguity in the patent’s description of the basic and novel properties of its invention, no matter how marginal, the phrase “consisting essentially of” would be considered indefinite. Nor are we requiring that the patent owner draft claims to an untenable level of specificity. We conclude only that, on these particular facts, the district court did not err in determining that the phrase “consisting essentially of” was indefinite in light of the indefinite scope of the invention’s basic and novel property of a “better drying time.”¹¹

As such, patent owners may be able to defend their patents from indefiniteness challenges along the lines set forth in this case by distinguishing from the facts thereof, or by filing a reissue application to restructure any “consisting essentially of” claims included therein.

¹Appeal Nos. 2017-2149, 2017-2152, 2017-2153, 20172202, 2017-2203, and 2017-2206 (Fed. Cir. Oct. 10, 2019).

²*Id.*, slip op. at 2, 33. A number of other issues were decided in the appeal. This article deals only with the indefiniteness of the “consisting essentially of” transitional phrase.

³*PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998).

⁴A claim is invalid for indefiniteness if its language, read in light of the specification and prosecution history, “fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014).

⁵*HZNP Medicines*, *supra* n.1, slip op. at 26.

⁶Namely, *PPG Indus. and AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003).

⁷*HZNP Medicines*, *supra* n.1, slip op. at 28.

⁸*Id.* at 32.

⁹Dissent at 9.

¹⁰*Id.* at 10.

¹¹*HZNP Medicines*, *supra* n.1, slip op. at 33

Haynes and Boone Wins Final ITC Determination Against Patent Infringer for Client PTS Diagnostics

Haynes and Boone partners Ken Parker and Robert Ziemian led the trial team that obtained the victory for PTS Diagnostics. The team also partners Charlie Jones and Rich Rochford, Counsel Aaron Taggart; and Associates Tiffany Cooke and Eva Zhao.

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ITC Intelligence Report Lists Haynes and Boone Among Most Active Firms Representing Complaints

Haynes and Boone is listed among leaders in U.S. ITC Section 337 investigations in a new ITC Intelligence Report from Patexia Inc., an intellectual property analytics company.

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Managing IP Selects Haynes and Boone as Patent Prosecution Firm of the Year - U.S. South - in 2020

Managing Intellectual Property, which covers IP news and developments worldwide, has named Haynes and Boone as the leading patent prosecution firm in the southern U.S. in 2020.

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Haynes and Boone Wins Gold National Ranking as Leading Trademark Firm, with Three of its Lawyers Dubbed Global Leaders

The 2020 edition of the *World Trademark Review 1000* directory of leading trademark professionals awarded Haynes and Boone a gold ranking as one of the top 11 firms in the U.S.

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59 Haynes and Boone Lawyers to be Honored in 2020 Chambers USA Directory

The 2020 edition of the *Chambers USA* legal directory will feature 59 Haynes and Boone lawyers and 17 practice areas. Six attorneys from the Intellectual Property Department were individually recognized:

- Purvi Patel Albers
- Jeffrey Becker
- Randall E. Colson
- Russell Emerson
- David McCombs
- Laura Beth Miller

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IP QUIZ

Trademark Trivia

Is there a likelihood of confusion?



According to the U.S. Trademark Trial and Appeal Board, the answer is NO.

The Board reversed the refusal to register applicant Medline Industries, Inc.'s mark on the Supplemental Register for the color green (Pantone 2274c) in connection with "medical examination gloves." The Examining Attorney refused registration based on a likelihood of confusion with a registration on the Supplemental Register for the color green (Pantone 7488U) covering "gloves for medical use" and "protective gloves for medical use."

The Board first held, as expected, that the goods are identical, as are the channels of trade and classes of purchasers, which tipped the scales heavily towards finding a likelihood of confusion.

The Board next considered the existence of similar marks in use on similar goods. Applicant submitted evidence of over forty different green medical gloves, arguing that the field was crowded. However, the Board clarified that "what is relevant...is evidence of the existence of third-party marks, not simply the presence in the marketplace of third-party goods bearing some shade of the color at issue." The Board found no evidence in the record that the third-party medical gloves would be perceived as marks. However, the Board found that these numerous "third-party non-trademark uses of shades of green on medical gloves tend to impair the cited Supplemental Register

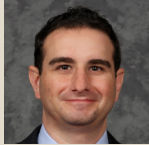
mark's ability to acquire distinctiveness, and to limit its scope of protection if it did acquire distinctiveness." The Board held that "[w]idespread use of a color in a particular market impairs an entity's ability to show that its proposed color mark has acquired distinctiveness in that market," and thus the numerous third-party green gloves weighed against a likelihood of confusion.

In assessing the similarity of the marks, the Board found that, because both the applicant's mark and the registered mark include a Pantone number in the mark description, each only claims rights to a specific shade of green, not the general color green. Comparing these shades of green, the Board found "significant differences in visual appearance" between the two shades, with the applicant's mark being a "subdued, pale shade that would be perceived as somewhere on the outer periphery of the green color family" and the registered mark being "a bright, attention-grabbing hue that is squarely within the green color family." Thus, the dissimilarity of the marks strongly supported a finding that confusion was not likely.

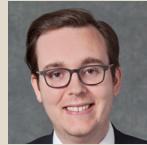
In balancing the factors, the Board found that confusion was not likely and reversed the refusal to register.

In re Medline Industries, Inc., 2020 USPQ2d 10237 [precedential].

If you have any questions, please visit the Haynes and Boone [Intellectual Property Law](#) page of our website.



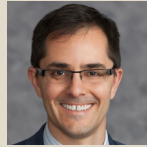
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