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**ALL THE NEWS THAT’S FIT TO OWN: HOT NEWS ON THE INTERNET & THE COMMODIFICATION OF NEWS IN DIGITAL CULTURE**

Clay Calvert
Kayla Gutierrez
Christina Locke

**KINGSDOWN TWENTY YEARS LATER: WHAT IT TAKES TO PROVE INEQUITABLE CONDUCT IS NO CLEARER**

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ALL THE NEWS THAT’S FIT TO OWN:
HOT NEWS ON THE INTERNET & THE COMMODIFICATION OF NEWS IN DIGITAL CULTURE

By Clay Calvert
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INTRODUCTION

Thousands of hard copies of newspapers across the country—particularly editions of college newspapers—are reported pilfered each year. But just as the theft of print newspapers can occur at news racks, can online news stories that flow on the Internet also be stolen?

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That question, as this article demonstrates, is no idle academic query or a wasted exercise in verbal gymnastics distinguishing newspapers from news and news stories. In fact, it is at the heart of some battles now being fought over news on the Internet.

It is, of course, a fundamental tenet of copyright law in the United States that ideas cannot be owned. Similarly, as the United States Supreme Court observed nearly twenty years ago, “facts are not copyrightable,” adding that this proposition is “universally understood.” The implication of these twin principles for the practice of journalism and the often poorly explicated concept of news itself is that while “the words and arrangement of a news story would be copyrightable expression,” when they are assembled in an original manner and fixed in a tangible medium of expression, “the underlying news itself—the facts and events being recounted—of course could not be the subject of copyright protection.” In other words, as one federal appellate court put it, “[c]opyrightable material often contains uncopyrightable elements within it.” This would seem to protect rewrites of news articles when those rewrites involve re-ordering, re-working, and using the underlying facts—the uncopyrightable underlying “news element,” as the United States Supreme Court once called it—in different ways.

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2 As Elvis Costello once so aptly put it in a way that attorneys and long-winded legal scholars would be wise to obey, “spare us the theatrics and the verbal gymnastics.” Elvis Costello, The Loved Ones, on IMPERIAL BEDROOM (Rykodisk 1982).
5 Id.
6 See generally Bruce D. Itule & Douglas A. Anderson, NEWS WRITING & REPORTING FOR TODAY’S MEDIA 11 (7th ed. 2007) (writing that “the definition of news is elusive,” observing that definitions of news range from “[s]omething you haven’t heard before” to “[w]hat editors and reporters say it is,” and ultimately determining that “[w]hatever it is, news is an extremely complex term, and it is different things to different people”).
9 Myers, supra note 7, at 675.
10 Nat’l Basketball Ass’n v. Motorola, Inc., 105 F.3d 841, 849 (2d Cir. 1997).
11 Int’l News Serv., 248 U.S. at 234.
But that does not end the legal inquiry. Copyright principles do not provide the only legal framework for considering possible redress when one news agency or news service believes another company is, in a nutshell, ripping off its news articles. As the Associated Press proved in 2009, the common law tort of hot news misappropriation provides a viable method—at least in those states that recognize it and do not view it as pre-empted by the federal Copyright Act and in those circumstances that fall within its rather narrow confines—of fighting back against the alleged digital piracy of news stories online where, as one law journal article contended, the “ease of free riding on the investment of others via Internet-related technological advances threatens to be a serious disincentive to investment in the development of data-based informational products.”

In July 2009, the Associated Press settled for an undisclosed dollar amount a lawsuit asserting that, in layperson’s terms, its news content was being stolen by the All Headline News Corp. (hereinafter “AHN” or “All Headline News”), a Florida-based business that bills itself as “a leading provider of news, weather, and other content for web sites, wireless, digital signage, interactive applications, broadcast

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12 The tort of hot news misappropriation originally was a “creature of the federal common-law,” and “while the federal common-law no longer provides the source for the action of misappropriation, state law can provide the basis for such protection.” Schuchart & Assocs. v. Solo Serve Corp., 540 F. Supp. 928, 942, n.9 (W.D. Tex. 1982).

13 See 17 U.S.C. § 301 (2006) (providing, in general, for the preemption of “all legal or equitable rights that are equivalent to any of the exclusive rights within the general scope of” federal statutes governing copyright, and governing preemption issues of federal copyright law). Importantly, courts have held that the hot news misappropriation tort is “a branch of the unfair competition doctrine not preempted by the Copyright Act.” Fin. Info., Inc. v. Moody’s Investors Serv., Inc., 808 F.2d 204, 209 (2d Cir. 1986).

14 See infra note 81 and accompanying text (identifying the five elements of this cause of action that, according to courts within one federal appellate circuit, must be demonstrated in order for a plaintiff to succeed).


The AP, which conversely trumpets itself as “the largest and oldest news organization in the world” and “the backbone of the world’s information system serving thousands of daily newspaper, radio, television and online customers,” alleged in its January 2008 complaint that “AHN has no reporters and is simply a vehicle for copying news reports and misappropriating news gathered and reported by real news services such as AP.” As such, the AP asserted that AHN was “free-riding on AP’s significant and costly efforts to collect, report and transmit newsworthy information,” thereby creating a low-cost news service with “no journalistic infrastructure” that “directly competes with AP’s own news services.”

Although the AP’s complaint included multiple causes of action, such as breach of contract, trademark infringement, and copyright infringement, the most journalistically intriguing legal theory upon which the AP sued AHN was for hot news misappropriation under the common law of New York. In Associated Press v. All Headline News Corp., the AP successfully reached back in time and stretched a ninety-one-year-old precedent—one developed many decades before the Internet enabled the type of appropriation engaged in by AHN—found in the United States Supreme Court’s opinion in International News Service v. Associated Press.

In that 1918 decision, a majority of the United States Supreme Court determined that, in situations of direct competition where “both parties are seeking to make profits at the same time and in the same field,” news that is gathered by one of those parties “must be

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19 Id.
21 Id. at 24.
22 Id. at 19.
23 Id. at 19.
24 See id. at 26–27 (setting forth the AP’s seventh cause of action for breaches of contract).
25 See id. at 22–23 (setting forth the AP’s fourth cause of action for infringement of a registered trademark).
26 See id. at 20–21 (setting forth the AP’s second cause of action for copyright infringement).
27 See id. at 19–20 (setting forth the AP’s first cause of action for hot news misappropriation).
29 248 U.S. 215 (1918).
30 Id. at 236.
regarded as quasi property”\textsuperscript{31} that possesses “an exchange value to one who can misappropriate it.”\textsuperscript{32} In particular, the Court reasoned that the “peculiar value of news is in the spreading of it while it is fresh,”\textsuperscript{33} implying that when news is no longer “fresh”—a term not defined in \textit{International News Service}—the property right that one news service possesses against another disappears.

Rejecting as “untenable”\textsuperscript{34} the notion that “news is abandoned to the public for all purposes when published in the first newspaper,”\textsuperscript{35} the Supreme Court focused instead on fiscal concerns—the concept of unfair competition,\textsuperscript{36} “the business of making [news] known to the world,”\textsuperscript{37} and the equitable principle “that he who has fairly paid the price should have the beneficial use of the property.”\textsuperscript{38} Put more bluntly, because the AP in \textit{International News Service} had gathered and distributed news due to “a large expenditure of money, skill, and effort,”\textsuperscript{39} it deserved to profit from the “novelty and freshness”\textsuperscript{40} of its news and to stop a free-riding rival news service from “misappropriating it for the purpose of disposing of it to his own profit and to the disadvantage of”\textsuperscript{41} the Associated Press.

The case has thus been called by one law professor “the most famous reap/sow case”\textsuperscript{42} of the twentieth century, drawing from Justice Mahlon Pitney’s underlying concern for fairness that defendant \textit{International News Service} was “endeavoring to reap where it has not sown.”\textsuperscript{43} As Professor John Tehranian aptly summed up the majority ruling, \textit{International News Service} “granted news organizations temporary ownership of factual information in order to preserve their incentive to expend resources on news-gathering without fear of having rivals free ride on the information by scooping them without payment.”\textsuperscript{44}

\textsuperscript{31} Id. (emphasis added).
\textsuperscript{32} Id. at 238.
\textsuperscript{33} Id. at 235.
\textsuperscript{34} Id. at 240.
\textsuperscript{35} Id.
\textsuperscript{36} See id. at 235 (“[I]t seems to us the case must turn upon the question of unfair competition in business.”).
\textsuperscript{37} Id.
\textsuperscript{38} Id. at 240.
\textsuperscript{39} Id. at 238.
\textsuperscript{40} Id.
\textsuperscript{41} Id. at 240.
\textsuperscript{43} \textit{Int’l News Serv.}, 248 U.S. at 239.
The “practical needs and requirements of the business” of making and disseminating news thus prevailed before the Supreme Court in *International News Service*. The case represents, as Professor Dale P. Olson put it a decade ago, “the genesis of misappropriation,” and it “formed—and continues to form—the basic contours of the doctrine of misappropriation of publicly disclosed trade values.” The continuing formation and evolution of that doctrine and, in particular, the tort of hot news misappropriation in 2009 in *Associated Press v. All Headline News Corp.* is the focus of this article. And although the federal common law that gave rise to the *International News Service* decision is now long defunct, the hot news misappropriation tort is alive and well in the age of the Internet in New York.

Part I of this article analyzes the case of *Associated Press v. All Headline News Corp.*, tracing it from the filing of the complaint through the July 2009 settlement. Importantly, it uses the actual pleadings and briefs filed by the parties, as well as other background information about the parties, to better contextualize the story behind the case. Part II then explores the legal precedent underlying the hot news misappropriation theory that was at issue in the case, as well as some of the criticisms and comments that legal scholars have launched against it over the years. Next, Part III goes beyond a pure legal analysis to explore the potential implications of the hot news misappropriation doctrine for a digital culture in which freshness and up-to-the-minute information is privileged and prized. Part III also identifies the different interests at stake in cases like *Associated Press v. All Headline News Corp.* Finally, Part IV concludes by suggesting future avenues of research related to the conduct of companies such as All Headline News Corp., including analyzing their behavior from an ethical perspective, not simply a legal one. In brief, journalism ethicists should analyze both the case and hot news doctrine from their viewpoint and position.

I. Re-Writing The News or Re-Writing The Law? The Associated Press’s Battle Against All Headline News Corp.

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47 *Id.*
"AP is a leader in protecting intellectual property rights through monitoring, licensing and enforcement efforts."\(^{49}\)

High-profile evidence buttressing that assertion, which the Associated Press conveys on its website,\(^{50}\) was on full display in 2009 when the news service contended that artist Shepard Fairey engaged in a “willful and blatant violation of The AP’s copyright in a photograph of President Obama”\(^{51}\) that Fairey used to create his so-called Obama Hope poster.\(^{52}\) Tom Curley, president and chief executive officer, proclaimed that the AP’s countersuit against Fairey—the artist had initially sued the AP—"is about protecting the content that The Associated Press and its journalists produce every day, with creativity, at great cost, and often at great risk."\(^{53}\)

Beyond this skirmish over a now iconic image,\(^{54}\) the Associated Press in July 2009 announced it was “creating a way to track and control the distribution of its articles online.”\(^{55}\) The move arose because, as the \textit{Wall Street Journal} reported, “some bloggers and other Web sites run stories without permission.”\(^{56}\) Tom Curley, AP’s chief executive, incorporated language in a press release echoing the reap/sow principle at the heart of \textit{International News Service},\(^{57}\) emphasizing that the AP has “stood by too long and watched other people make money off the hard work of our journalists. We have decided to draw a line in concrete.”\(^{58}\)


\(^{50}\) Id.


\(^{52}\) See generally Christopher Borrelli, \textit{Street Artist Fairey at a Crossroad}, \textit{CHI. TRIB.}, Feb. 9, 2009, at 3 (reporting on “an allegation from The Associated Press that Fairey infringed its copyright by appropriating one of its photos for the ‘Hope’ poster”).


\(^{54}\) See James C. Goodale, \textit{What’s Fair is Fair. But What is Fair?}, 241 N.Y. L.J. 3, (2009) (“Mr. Fairey downloaded the photo from the Internet, cast Mr. Obama in red, white and blue tones, and added ‘Hope’ underneath. The poster became a campaign icon.”) (emphasis added).


\(^{56}\) Id.

\(^{57}\) See supra notes 43-45 and accompanying text (discussing this principle within the context of \textit{International News Service}).

In addition to such policing and monitoring of its content on the Internet via built-in beacons that track where a story moves and posts online,\textsuperscript{59} the AP demonstrated its resolve on intellectual property matters in very different way in \textit{Associated Press v. All Headline News Corp.}\textsuperscript{60} In particular, it used an aging doctrine that was developed at a time when print newspapers ruled the day.

AHN, based in Wellington, Florida, is owned by a former police officer named Jeffrey Brown, who founded the company after a customer of another website he operated, BridalClicks.com, asked for news content.\textsuperscript{61} He had no previous journalism experience.\textsuperscript{62} Despite the lack of relevant bona fides, the business took off fast, and Brown was quoted in 2008 as stating that “despite the troubling and uncertain economy, we’re on track to double our revenues this year.”\textsuperscript{63}

With AHN’s operation apparently becoming a success, AP filed its lawsuit against AHN and Brown in federal court in New York in January 2008.\textsuperscript{64} The AP alleged that AHN hires poorly paid individuals, instructs them to surf the Internet for new stories, and then has them either copy the stories verbatim or re-write them, all the while carefully omitting any identifying information about their origin.\textsuperscript{65} In its First Amended Complaint, filed in April 2008, the AP asserted that AHN’s writers “do no independent research and newsgathering in preparing news stories.”\textsuperscript{66} In fact, the AP contended that—like so many businesses today in the United States—AHN off-shored part of the re-writing process to people in Malaysia, with the cost savings allowing AHN to sell what once really were the AP’s stories at a price to subscribers cheaper than the AP could sell them.\textsuperscript{67} Once the stories are edited, the AP claimed they are “aggregated by AHN into a news feed which it then distributes to its customers and displayed and/or distributed via AHN’s servers.”\textsuperscript{68}

http://www.ap.org/pages/about/whatsnew/wn_072309a.html.
\textsuperscript{59} \textit{Id.} (stating that the AP will be “bundling its text stories in an ‘informational wrapper’ that will include a built-in beacon to monitor where stories go on the Internet”).
\textsuperscript{60} \textit{See} Associated Press v. All Headline News Corp., 608 F. Supp. 2d 454 (S.D.N.Y. 2009).
\textsuperscript{62} \textit{Id.}
\textsuperscript{63} \textit{Id.}
\textsuperscript{64} \textit{See} Complaint, \textit{supra} note 20.
\textsuperscript{65} \textit{Id.} at 2-3.
\textsuperscript{66} First Amended Complaint at 16, Associated Press v. All Headline News Corp., 608 F. Supp. 2d 454 (S.D.N.Y. 2009) (No. 08 Civ. 323) [hereinafter First Amended Complaint].
\textsuperscript{67} \textit{Id.} at 20.
\textsuperscript{68} \textit{Id.} at 16.
Striking to the economic heart of its hot news misappropriation claim, the AP asserted that AHN’s conduct is likely to usurp AP’s business relationships and opportunities. AHN’s “news service” directly competes with AP’s own services. Both services are sold to the same potential customer base. Most customers of news service only carry one service. When a company or entity decides to subscribe to AHN’s “news service,” this effectively excludes AP from selling its service to that company or entity.69

Asking the court to enjoin AHN’s actions, the AP closed its argument on the hot news misappropriation cause of action by conjuring up the proverbial parade of horrors that would result in the absence of such a judicial decree:

If Defendants are not enjoined from misappropriating AP’s efforts and investments in this manner, the acts of Defendants and other free-riders will so reduce AP’s incentive to gather and report the news that the existence and/or quality of the news services that AP provides to AP Members, subscribers and other licensees, and thereby to the public, will be substantially threatened.70

AHN, of course, attempted to paint the case as a battle in the David-and-Goliath tradition, arguing that “this case is an attempt by Plaintiff Associated Press to crush by weight of litigation a small company that it views as a competitor in the business of online news distribution.”71 But it defended against the hot news misappropriation cause of action not primarily on the merits of the case, but rather by claiming that the law of Florida—not New York—applied, and Florida did not recognize such a legal theory.72 As the attorneys for AHN and Brown wrote, “Defendants are not aware of any Florida state court opinions that have recognized a theory of misappropriation like that asserted by Plaintiff here.”73 AHN also asserted that the International News Service opinion itself was no longer good law,74 as it claimed the hot news misappropriation doctrine found in International News Service was part of the federal common law that was later eliminated.

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69 Id. at 20.
70 Id.
71 Memorandum in Support of Defendants’ Motion to Dismiss Under Federal Rule of Civil Procedure 12 at 1, All Headline News Corp., 608 F. Supp. 2d 454 (No. 08 Civ. 323).
72 Id. at 3-10.
73 Id. at 9.
74 Id. at 7, n.2.
by the U.S. Supreme Court in *Erie Railroad Co. v. Tompkins.*\(^{75}\)

These arguments failed to gain traction, however, with the court. In February 2009, U.S. District Judge P. Kevin Castel refused to dismiss the Associated Press’s hot news misappropriation claim, as he determined that the cause of action “remains viable under New York law”\(^{76}\) and is not pre-empted by federal copyright law.\(^{77}\) Quoting from a 1997 ruling by the United States Court of Appeals for the Second Circuit that also recognized such a theory under New York law,\(^{78}\) Judge Castel articulated five elements that must be present for a successful cause of action for hot news misappropriation:

(i) a plaintiff generates or gathers information at a cost; (ii) the information is time-sensitive; (iii) a defendant’s use of the information constitutes free riding on the plaintiff’s efforts; (iv) the defendant is in direct competition with a product or service offered by the plaintiffs; and (v) the ability of other parties to free-ride on the efforts of the plaintiff or others would so reduce the incentive to produce the product or service that its existence or quality would be substantially threatened.\(^{79}\)

Judge Castel did not apply these elements to the facts of the case, however, as AHN’s motion to dismiss focused only on the pre-emption argument and the contention that Florida law, rather than New York, controlled.\(^{80}\)

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\(^{75}\) *Id.* For an in-depth discussion of the *Erie* Doctrine, see generally Joseph R. Oliveri, *Converse-Erie: The Key to Federalism in an Increasingly Administrative State*, 76 GEO. WASH. L. REV. 1372, 1375-76 (2008) (observing that “the *Erie* doctrine – the cornerstone of analysis of the relationship between federal and state law in federal courts – provides that federal courts, except in matters governed by the Constitution or federal statutes, shall apply the substantive law of the forum state,” and adding that in *Erie*, “the Supreme Court overturned the previous rule of *Swift v. Tyson*, rejecting the notion of a ‘federal general common law’ to which federal courts had previously looked to find the applicable rule of decision”) (citations omitted).


\(^{77}\) *Id.*

\(^{78}\) See Nat’l Basketball Ass’n v. Motorola, Inc., 105 F.3d 841 (2d Cir. 1997) (involving the application of the hot news misappropriation tort in the context of a dispute about the transmission of scores and other data about NBA games in progress via paging devices).

\(^{79}\) *All Headline News Corp.*, 608 F. Supp. 2d at 461 (quoting *Motorola*, 105 F.3d at 845).

\(^{80}\) See *All Headline News Corp.*, 608 F. Supp. 2d at 458 (writing that the motion to dismiss the hot news misappropriation cause of action was based “on two grounds,” including the contention that “choice of law requires that plaintiff’s claim of misappropriation of hot news be considered under the law of Florida, which, defendants contend, has rejected such a cause of action” and the assertion “that a claim for misappropriation of hot news is preempted by the federal Copyright Act”).
In lauding Judge Castel’s decision, the AP’s director of media relations, Paul Colford, stated the “ruling reaffirms the viability of the hot news misappropriation doctrine, and thereby protects AP’s investments in news gathering and reporting against copying by free-riders.” Colford also pointed out that the case was not simply about the AP’s right to make money, but the public’s right to receive information, as he stated that “by preserving the economic incentive to gather and report hot news, this decision will further the public interest in having access to such news and also encourage the efforts of journalists.” This framing of the case attempts to place the AP in the noble position of protecting the public interest rather than casting it as a greedy entity trying to eliminate a competitor.

Significantly, when the case settled, the agreement between the parties included a provision under which AHN acknowledged that “the tort of ‘hot news misappropriation’ has been upheld by other courts and was ruled applicable in this case by U.S. District Court Judge P. Kevin Castel.” This appears to be a warning shot fired by the AP—a shot targeting other news services and news aggregators like AHN—that the AP will use the same theory again to challenge their actions. Ethan K. Ackerman, a Washington, D.C.-based attorney who has worked in the U.S. Senate as technology counsel, observed “settlements don’t validate legal theories, court opinions do. That said, part of the settlement required AHN to pseudo-admit the viability of the hot news misappropriation doctrine.” In its own—albeit much shorter—press release, AHN acknowledged paying the AP an

82 Id.
84 See Order of Dismissal at 1, All Headline News Corp., 608 F. Supp. 2d 454 (No. 08 Civ. 323) (providing, in relevant part, that the court was “advised that all claims asserted herein have been settled,” and dismissing the case without prejudice to reopening it within 60 days if the settlement was not consummated).
86 See generally Barb Palser, Is It Journalism?, AM. JOURNALISM REV., June 2002, at 62, ## (discussing the concept of news aggregators and, in particular, Yahoo! News).
undisclosed amount of money, but it continued to deny the AP’s allegations. 88

With this analysis of the Associated Press v. All Headline News case in mind, the next part of this article turns to the development of the tort at issue in it, as well as a review of scholarly legal commentary about it.

II. THE EVOLUTION OF THE HOT NEWS MISAPPROPRIATION TORT: A REVIEW OF LEGAL PRECEDENT AND SCHOLARLY LITERATURE

The U.S. Supreme Court’s decision in International News Service v. Associated Press was handed down in 1918, a time when consolidation in the print newspaper industry was first beginning. 89 Media mogul William Randolph Hearst had created what would become the International News Service (“INS”) some twelve years earlier to compete against the Associated Press, which had been formed in the mid-1800s. 90 The dispute at issue between the two news services began when INS, lacking international cables connecting Europe to the United States, began “clipping news from AP member newspapers” 92 and “copying it from AP bulletin boards.” 93 By pilfering AP-based content from early editions of East Coast newspapers, INS was actually able to beat the AP, given time-zone differences, to the West Coast newspapers with the AP’s own content. 94 As Professor Paul W. Sullivan observes in an excellent

89 “Let Munsey Kill It!”: The Birth of the Newspaper Chain, in 1 AMERICAN DECADES 350, 350-51 (Vincent Tompkins ed., 1996) (writing that “[i]n 1890 New York had fifteen English-language daily newspapers. By 1932 it had half that number. The twentieth-century trend toward newspaper consolidation began in earnest during the century’s first decade” and pointing out that “[i]n upstate New York Frank E. Gannett bought a partial interest in the Elmira Gazette in 1906 and then merged it with the Elmira Star. In the 1910s he bought two papers in Ithaca and combined them, and in the 1920s acquired others in Rochester, Utica, and in other northeastern states, laying the groundwork for the largest chain in the country”).
93 Id.
94 Id.
examination of the case that should be read by anyone wanting a complete analysis of it, the “AP objected that some of its own members in the western part of the country were not receiving the news as quickly as INS customers were receiving the pirated news.”

Importantly, the AP did not argue that its stories were copyrighted. As Professor Eric Easton writes, the “AP argued that securing copyright for its dispatches was impractical and that those dispatches were beyond the scope of the Copyright Act. AP’s property interest lay exclusively in protecting its business from freeriders.”

As described in the Introduction, Justice Pitney and the majority of the court sided with the Associated Press, expressing deep concern about what it considered to be unfair competition by INS and finding a quasi property right in the fresh news stories that it spent time, money, and labor to gather and produce. The property interest held by the AP, Justice Pitney made clear, was not as against all of the world or the newspaper reading public, but only as against its competitors, writing:

The question here is not so much the rights of either party as against the public but their rights as between themselves. And although we may and do assume that neither party has any remaining property interest as against the public in uncopyrighted news matter after the moment of its first publication, it by no means follows that there is no remaining property interest in it as between themselves. For, to both of them alike, news matter, however little susceptible of ownership or dominion in the absolute sense, is stock in trade, to be gathered at the cost of enterprise, organization, skill, labor, and money, and to be distributed and sold to those who will pay money for it, as for any other merchandise.

From a public policy perspective that centers on an unenumerated First Amendment right to receive speech, this is an

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95 Id.
97 See supra footnotes 43-45 and accompanying text (describing Justice Pitney’s opinion for the majority of the high court).
99 See Bd. of Educ., Island Trees Union Free Sch. Dist. No. 26 v. Pico, 457 U.S. 853, 867 (1982) (opining that “the right to receive ideas is a necessary predicate to the recipient’s meaningful exercise of his own rights of speech, press, and political freedom”); Griswold v. Connecticut, 381 U.S. 479, 482 (1965) (writing that “the right of freedom of speech and press includes not only the right to utter or to print, but the right to distribute, the right to receive, the right to read”); Martin v. Struthers,
important dichotomy. It suggests that the majority opinion is not intended to deprive the public of news but is, instead, only intended to provide profit and incentive for the gathering of that news by depriving another business entity—a rival/competitor—from profiting from it. In other words, the hot news misappropriation doctrine that was to emerge from the case was not to be used against the public, but against rival businesses.

The court also made it clear that, even as against a rival/competitor, the quasi property interest held in news is ephemeral, lasting only so long as the news at issue is fresh. As Justice Pitney wrote:

[T]he view we adopt does not result in giving to complainant the right to monopolize either the gathering or the distribution of the news, or, without complying with the copyright act, to prevent the reproduction of its news articles; but only postpones participation by complainant’s competitor in the processes of distribution and reproduction of news that has not gathered, and only to the extent necessary to prevent that competitor from reaping the fruits of complainants efforts and expenditure, to the partial exclusion of complainant, and in violation of the principle that underlies the maxim sic utere tuo, etc.100

Finally, Justice Pitney and the majority attempted to make it clear that the misappropriation cause of action could not be used to prevent or thwart one competitor from taking “the news of a rival agency as a ‘tip’ to be investigated, and if verified by independent investigation the news thus gathered is sold.”101 The Court here drew another dichotomy, this time between the uses that a rival could properly make of a competitor’s fresh news content:

- **Permissible**: Use the information as a tip to be independently investigated and corroborated for one’s own story.
- **Forbidden**: “the bodily appropriation of another’s labor in accumulating and stating information.”102

319 U.S. 141, 143 (1943) (writing that the First Amendment freedom to distribute literature “necessarily protects the right to receive it”).


102 *Id.* (quoting Associated Press v. Int’l News Serv., 245 F. 244, 247 (2d Cir. 1917)).
In summary, the majority opinion, although failing to clearly delineate the precise elements of the hot news misappropriation tort that would evolve from the International News Service case, seemed to place three limitations on it, at least in the opinion of the authors of this article:

1. It can only be used by one rival against another rival, not against the public.
2. The quasi property right in news that is instilled by the tort does not last forever against a rival, but merely “postpones participation” in the news by the rival, hence the idea that it merely is a “hot news” tort.
3. A rival is free to use a competitor’s fresh news for purposes of providing it with a tip or lead to be independently investigated and produced as its own news story.

The majority opinion in International News Service has been the subject of much legal commentary and writing over the years. For instance, University of Chicago Law Professor Richard Epstein observes that Justice Pitney’s opinion “rests upon the idea of property rights in news,” rights that the AP possessed in its fresh news as against a direct competitor, INS. These rights, however, last only while the news is fresh and, in addition, only against a direct competitor. This echoes two of the three limitations set forth above.

The notion of finding a property right in news, however, is one of the fundamental reasons that International News Service is criticized by legal scholars. For example, Professor Leo J. Raskind blasts the “‘quasi-property’ foundation on which the INS majority relied” in order to side with the AP and divine a theory of misappropriation as “question-begging.” Raskind suggests that the majority’s concern with unfair competition—the “unique commercial ‘dirty trick,’” in Raskind’s words, in which INS “took AP news in

105 Id. at 92.
106 See id. at 114 (observing that Justice “Pitney describes the defendant’s interest in its news as ‘quasi property,’ which is good only for a short period of time (less than a day) and then only against the direct competitor of the plaintiff”).
108 Id.
109 Id. at 881.
order to have a saleable product" and passed it off as its own work—should not have led it to adopt a property foundation for grounding the opinion. As Raskind writes:

Introducing the concept of "quasi-property" diverts the inquiry. The defect in the majority opinion is that it relies on a legal doctrine relating to the marketing side of competition [passing off] and cloaks that doctrine with the status of property. The majority then sought to provide an analysis of a taking of an undefined property interest in the context of a competitive market in which taking is the very nature of the relationship.\

Others also object to the notion of using a property right to protect information. Professor Michael Pendleton describes what he calls "the inappropriateness of property as a conceptual/legal device for ordering rights among the groups of persons who have legitimate interests in protecting as well as accessing (within limits) the substantial labour, skill, effort and investment of time and money involved in creating information "products.""

Another criticism of the International News Service decision relates to the separation of powers and roles between judges and legislators. As Professor Douglas G. Baird writes, "[critics] argue that judges are poorly situated to identify the policies at stake in an intellectual property dispute and that judges therefore should not recognize intellectual property rights until the legislature has done so." Supporting this proposition that legislators should create the law here is the idea that "the federal system of intellectual property derives from the clause of the Constitution that gives Congress the power to give authors and inventors exclusive rights to their writings and discoveries for a limited time for the purpose of promoting 'the Progress of Science and useful Arts.'" In this line, Professor L. Ray Patterson observes that International News Service actually "can be viewed as a copyright case in the guise of unfair competition" because, although the AP’s stories were copyrightable, it had not copyrighted them. As a copyright case in the United States, it would be governed by legislative rules, not by a court-created doctrine that

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110 Id. at 885.
111 Id. at 886-87.
114 Id. at 415 (quoting U.S. CONST. art. I, § 8, cl. 8).
116 Id. at 58-59.
was, as Professor Raskind contends, launched “in an ad hoc fashion” to fill a vacuum in favor of the Associated Press.\footnote{Raskind, supra note 107, at 881.}

More generally but certainly not less importantly, the majority opinion has been criticized as being at odds with the First Amendment freedom of speech. As Professor Diane Zimmerman writes about the majority’s rationale that hard work and effort in gathering news should be rewarded with property rights for exclusive use:

Taken at face value, this principle suggests that property rules are appropriately applied whenever someone exploits for profit information generated by the personality, activities, or intellectual efforts of someone else – and that the First Amendment is not offended by the requirement that the user first bargain for that right with the source of the value. Certainly, no evidence suggests that First Amendment jurisprudence has ever accepted this view.\footnote{Diane Leenheer Zimmerman, Information as Speech, Information as Goods: Some Thoughts on Marketplaces and the Bill of Rights, 33 WM. & MARY L. REV. 665, 722 (1992).}

Given these criticisms of the opinion, it is not surprising that the justices themselves split in \textit{International News Service}. In particular, Justice Louis Brandeis dissented at length,\footnote{Int’l News Serv. v. Associated Press, 248 U.S. 215, 248-267 (1918) (Brandeis, J., dissenting).} while Justice Oliver Wendell Holmes, Jr. issued a very brief concurrence that was joined by Justice Joseph McKenna.\footnote{Id. at 246-248 (Holmes, J., concurring).} Brandeis, who parsimoniously defined news as “a report of recent occurrences,”\footnote{Id. at 249 (Brandeis, J., dissenting).} objected to the idea that news is property. He opined:

An essential element of individual property is the legal right to exclude others from enjoying it. If the property is private, the right of exclusion may be absolute; if the property is affected with a public interest, the right of exclusion is qualified. But the fact that a product of the mind has cost its producer money and labor, and has a value for which others are willing to pay, is not sufficient to ensure to it this legal attribute of property. The general rule of law is, that the noblest of human productions – knowledge, truths ascertained, conceptions, and ideas – become, after voluntary communication to others, free as the air to common use.\footnote{Id. at 250.}

Brandeis also emphasized the danger to the right of the public to receive information that might be affected by extending a property

\footnote{\textsuperscript{117} Raskind, \textit{supra} note 107, at 881.\
\textsuperscript{119} Int’l News Serv. v. Associated Press, 248 U.S. 215, 248-267 (1918) (Brandeis, J., dissenting).\
\textsuperscript{120} Id. at 246-248 (Holmes, J., concurring).\
\textsuperscript{121} Id. at 249 (Brandeis, J., dissenting).\
\textsuperscript{122} Id. at 250.}
right in news, writing that an extension of property rights in news would lead to “a corresponding curtailment of the free use of knowledge and of ideas; and the facts of this case admonish us of the danger involved in recognizing such a property right in news, without imposing upon news-gatherers corresponding obligations.” Even if one were to extend such a right, Brandeis opined that such a decision should be made by a legislative body, not a judicial one, writing that “courts are ill-equipped to make the investigations which should precede a determination of the limitations which should be set upon any property right in news or of the circumstances under which news gathered by a private agency should be deemed affected with a public interest.”

Brandeis here seemed clearly concerned about potential harm to the public’s interest in news that might be caused by the majority’s holding. As Professor Geraldine Szott Moohr observes, Brandeis believed that “a new rule, unless carefully crafted, could injure the general public,” and thus “preferred a rule that encouraged free use of knowledge and ideas.”

A number of lower federal court opinions have since considered, to varying degrees, the viability and elements of the hot news misappropriation tort, but probably the most important opinion for purposes of the AP’s case against AHN, given its decision by the United States Court of Appeals for the Second Circuit, is National Basketball Ass’n v. Motorola, Inc. The case did not involve either news stories or news agencies, but centered instead on the real-time transmission of NBA game scores and statistics, taken from television and radio broadcasts of games in progress, via a paging device manufactured by Motorola and compiled by a service.

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123 Id. at 263.
124 Id. at 267.
126 Id. at 696.
128 105 F.3d 841.
called Sports Team Analysis and Tracking Systems. The case is important for two primary reasons: it recognized the existence of the hot news misappropriation tort in New York, and it articulated the same five elements of the cause of action spelled out by Judge Castel in the AP’s battle against AHN. In specifying those elements, the appellate court in Motorola called the hot news misappropriation tort “properly narrowed,” suggesting it is cabined quite closely by the Second Circuit.

The Second Circuit in Motorola interpreted the Supreme Court’s International News Service decision as founded on the goal of “the protection of property rights in time-sensitive information so that the information will be made available to the public by profit-seeking entrepreneurs.” As such, a viable hot news misappropriation claim will only survive preemption by the Federal Copyright Act if three key things are present: (i) the factual information at issue is time sensitive; (ii) there is a free-riding defendant; and (iii) there is a threat to the very existence of the product or service provided by the plaintiff. If it survives preemption, then a court will turn to the five elements of the tort itself.

III. NEWS, CULTURE AND CONTROL OF INFORMATION IN THE DIGITAL AGE: RAMIFICATIONS OF THE HOT NEWS MISAPPROPRIATION TORT

The hot news misappropriation tort originated in 1918 when people obtained their news via newspapers. Today, people get their news on the Internet, BlackBerrys and iPhones, as well as on television and even Twitter; an August 2008 report by the Pew Research Center for the People & the Press, for instance, found that “since the early 1990s, the proportion of Americans saying they read a newspaper on a typical day has declined by about 40%.” Conversely, the same survey found that “since 2006, the proportion of Americans who say they get news online at least three days a week has

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129 Id. at 843-44.
130 Id. at 845.
131 See supra note 81 and accompanying text.
132 Motorola, 105 F.3d at 848.
133 Id. at 853.
134 Id.
135 See Bob Franklin, The Future of Newspapers, 9 JOURNALISM STUD. 630, 630-31 (2008) (observing that today’s news content is delivered on “multiple media platforms” and “delivered by the Internet, pod casts and mobile telephony, more often than by newspaper delivery boys and girls”).
increased from 31% to 37%.”\textsuperscript{137}

We also live in a culture that thrives on the constant flow of information. As the website for Twitter states, “In countries all around the world, people follow the sources most relevant to them and access information via Twitter as it happens—from breaking world news to updates from friends.”\textsuperscript{138} Twitter has more than 20 million users,\textsuperscript{139} and as the \textit{Philadelphia Inquirer} observed, it has played “a growing role in disseminating news and organizing social and protest movements.”\textsuperscript{140} Might the use of the hot news misappropriation tort hinder or otherwise stanch the flow of news in such a faster-is-better world?

The dramatic changes in the speed at which news is conveyed, as well as the manner and mode of its receipt, can be a double-edged sword when intellectual property concerns are put into the equation. As Brian Cooper, the executive editor of the \textit{Telegraph Herald} in Dubuque, Iowa, recently observed:

In this Internet Age, with thousands of media outlets available at the click of a mouse, it is easier than ever to follow news events anywhere – from your hometown to the other side of the world. And it is also easier than ever for less-scrupulous outlets to appropriate that news and label it their own. Simply copy, paste, delete credit lines and – voila!\textsuperscript{141}

The Associated Press clearly is concerned about the ease at which such piracy can occur. It explains on its website why it has chosen to fight such battles so aggressively:

The Associated Press is a not-for-profit news cooperative that spends hundreds of millions of dollars every year gathering and sharing news of public interest from around the world. Licensing of this content by our members is critical to support our news operations. In the new digital content economy, however, a significant amount of AP news and news from AP members is used without permission or fair compensation. This situation has serious consequences: it dilutes the value of news for licensors and advertisers; it fragments and disperses content so widely that consumers end up relying on fragmented coverage to get their news

\begin{footnotesize}
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\item[137] \textit{Id.} at 4.
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despite the availability of comprehensive and authoritative coverage on a 24-hour basis.\footnote{142}

The AP’s actions likely have a large impact on so-called online news aggregating sites that, as attorney Jeffrey D. Neuburger writes, “have become ubiquitous on the Internet.”\footnote{143} An adjunct Professor at Fordham University School of Law, Neuburger points out the AP had previously been successful in obtaining settlements from other online news aggregators, including Google News and Verisign.\footnote{144} The AP’s win in federal court against AHN gives it more leverage to obtain further settlements in the future.

The potential ramifications of the AP’s current use of the hot news misappropriation tort stretch beyond the Internet to also affect television and radio journalism. As journalist Ken Robertson of the \textit{Tri-City Herald} in Washington State wrote in early 2009:

\begin{quote}
[It’s] common practice for radio and TV “news” readers to simply rip their stories off from their local newspaper, seldom bothering to credit the newspaper. This kind of theft has been commonplace for decades, and we newspaper people called it “rip and read” and joked that you could often hear the sound of the newspaper being folded on the air.\footnote{145}
\end{quote}

The practice of rip-and-read journalism on the radio may be increasing today, Robertson points out, as economic pressures mean that “radio and TV stations have even smaller staffs and thus even less time to do any original reporting and must rely more and more on rip and read.”\footnote{146} The AP’s newspaper clients—who pay for and work together with the AP—might now invoke the hot news misappropriation tort to forbid a local radio station from reading its stories on the air. “In Boise, Idaho, for example, the newspaper has told AP to forbid Boise radio and TV stations from using the newspaper’s news that is shared on the AP wire,”\footnote{147} Robertson writes.

Perhaps one of the most interesting questions involving the ramifications of \textit{Associated Press v. All Headline News Corp.} is whether the hot news misappropriation doctrine can be successfully used to squelch the speech of bloggers and citizen journalists who make use of online news like that conveyed by the AP. In other

\footnote{143} Posting of Jeffrey D. Neuburger to New Media & Technology Law Blog, http://newmedialaw.proskauer.com (Feb 26, 2009).
\footnote{144} Id.
\footnote{145} Id.
\footnote{147} Id.
words, will the hot news doctrine jeopardize the rapid and free exchange of information on what the U.S. Supreme Court once called “the vast democratic forums of the Internet?” Conversely, could a blogger who gets a scoop and breaks an important political news story be able to own the story, as it were, for a brief amount of time—as long it is “hot” news—and thereby stifle its dissemination to the wider public that depends on information conveyed by news services like the Associated Press? This is particularly important because, as Paul Farhi recently noted in the *American Journalism Review*:

Two of the biggest campaign trail scoops came not from a professional *journalist*, but from a blogger named Mayhill Fowler... Using her own money to follow the campaign around the country, the 61-year-old Fowler recorded Obama’s comments, made at a fundraiser in San Francisco, that “bitter” small-town voters “cling to guns and religion.” (Fowler never identified herself as a blogger; she was admitted to the closed event because she was an Obama contributor.) In June she encountered Bill Clinton at a rally in South Dakota and (again, failing to identify herself) asked about an unflattering profile of him in *Vanity Fair*. When Clinton launched into a tirade about the article's author, former *New York Times* reporter Todd Purdum (“sleazy!” “a scumbag!”), Fowler recorded that, too, and posted it online.

The answer to each of these questions would generally seem to be no. Why? Because the elements of the hot news misappropriation cause of action frame the tort so narrowly that most cases involving bloggers and citizen journalists on one side of the case, and a news service like the AP on the other side, simply would not fall within it. In particular, the fourth element of the tort as framed by Judge Castel in *Associated Press v. All Headline News Corp.*—and quoting the Second Circuit’s opinion in *National Basketball Ass’n v. Motorola*—requires the plaintiff to prove that “the defendant is in direct competition with a product or service offered by the plaintiffs.” The operations of the Associated Press or a news service like the United Press International simply are not in “direct competition” with the

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150 *Associated Press v. All Headline News Corp.*, 608 F. Supp. 2d 454, 461 (S.D.N.Y. 2009) (citing Nat’l Basketball Ass’n v. Motorola, 105 F.3d 841, 845 (2d Cir. 1997)).
services provided by a blogger or citizen journalist. The tort will only be successful if there are rivals in direct competition with each other.

Bloggers simply are not news services; both may supply important information that many people may consider to be news, but merely trafficking in similar information does not put them in direct competition. For instance, the Associated Press: 1) has more than 240 bureaus in 97 countries; 2) features 4,100 editorial, communications and administrative employees worldwide; 3) is owned by its 1,500 newspaper members; and 4) offers to its members news, photos, graphics, audio, and video.\(^\text{152}\) The stereotypical “blogger in his pajamas,”\(^\text{153}\) in comparison, may hit an important scoop from time to time, but he or she simply does not fulfill the same function—supplying newspapers, radio stations, and websites across the country with a constant and steady stream of information and different formats of mediated content—and consistently discover the same type of information that is dug up “by skilled reporters working beats day in and day out.”\(^\text{154}\) The AP can, to put it bluntly, be in many different places at one time, spanning the globe; the isolated blogger simply cannot. If the AP thus sued an individual blogger for taking one of its breaking news stories and posting it on the blogger’s website, as his or her own work, without either attribution or permission, the blogger certainly may have violated fundamental ethical tenets of journalism prohibiting plagiarism,\(^\text{155}\) but surely he or she has not committed the tort of hot news misappropriation.


\(^{153}\) This phrase is often used by the news media themselves to stereotype bloggers. See, e.g., Carl Carter, *Who Will Pay for the News? The Internet has Walloped Newspapers*, BIRMINGHAM NEWS (Ala.), Mar. 8, 2009, at 1F (contending that “bloggers in pajamas” cannot replace mainstream newspapers because those bloggers, along with “cell-phone photographers,” merely “piggyback on the real work done by real reporters”); Marc Fisher, *Politics 24/7: No One Can Hear You Scream*, WASH. POST, Oct. 14, 2007, at M1 (using the twin phrases “bloggers in their pajamas” and “pajamas media”); Logan Jenkins, *What’s the Future of the U-T? Read On, For Now*, SAN DIEGO UNION-TRIB., Jan. 26, 2009, at B2 (arguing in favor of the importance of traditional newspapers and contending that there is “no way can a loose network of bloggers in pajamas – or, for that matter, time-challenged broadcast outlets – match our concerted effort to inform in detailed depth”).


Ultimately, the Associated Press should be entitled to some form of qualified protection for its time, labor, and efforts in gathering breaking news, but not against bloggers or citizen journalists. The question really centers on defining the precise scope and range of the protection to which it should be entitled, given the competing interests at stake, against rival news services and news aggregators.

Those interests, in the opinion of the authors of this article, would seem to be at least threefold:

- the interests of the AP as the gatherer and creator of the news stories;
- the interests of the AP’s competitors and, in particular news aggregators; and
- the interests of the audience, recipients, and users of the news stories.\(^{156}\)

In light of these three interests, one might ask the following threshold question: Why is it important to protect the Associated Press in the first place, as it gathers information and writes news stories, when the public (the third possessor of an interest noted above) can obtain information from so-called citizen journalists and bloggers so readily today? Professor Michael Schudson of the University of California, San Diego, addressed that same issue in 2009, concluding that “matters of professional training, experience, and judgment are as or more important than ever”\(^{157}\) in the world of journalism and reasoning that “one need not idealize the newspaper press to recognize that to this day television, radio, and online news feed off the basic reporting that to an overwhelming extent comes from organizations whose economic survival no one knows how to guarantee.”\(^{158}\) In other words, there remains a fundamental difference in quality and content that separates professional journalists from bloggers and citizen journalists, even if that difference stems from a desire for economic survival.

According to a 2007 article published in *Journalism & Mass Communication Quarterly*:

> Aggregators produce little original news content, instead providing a platform for established news producers and access for users to multiple news sources. Arguably the most popular online news portal, Yahoo!News, allows users

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\(^{156}\) Cf. Pendleton, *supra* note 114, at 246 (identifying a very similar list of competing interests that must be taken into account in any dispute over intellectual property where time and labor are expended to gather and produce information).


\(^{158}\) *Id.*
to identify favorite topics—politics, business, science, entertainment—from various sources including Associated Press (AP), Agence France-Presse (AFP), Reuters, CNN, and others. A recent Pew study determined that 23% of online news consumers chose Yahoo!News, and while Yahoo!News usage has continued to increase, competitor aggregators, such as Google News, and online news providers, such as MSNBC.com and CNN.com, have lost users.\(^{159}\)

When a news aggregator has permission and explicit authorization from a company or news service to post links to its feeds, there clearly is no possibility of a hot news misappropriation claim. Lack of permission, however, raises the distinct possibility. While Judge Castel did not address the actual merits of such a scenario involving a news aggregator versus a news service,\(^ {160}\) it is clear that, as David Simon, a writer and former Baltimore Sun reporter, recently wrote in Columbia Journalism Review, “the relationships between newspapers and online aggregators—not to mention The Associated Press and Reuters—will have to be revisited and revised.”\(^ {161}\) The interests of society and the reading public—the third possessor of an interest identified above by the authors of this article—require the economic viability of professional news services because while “amateur journalists may have wise and clever things to say,”\(^ {162}\) they are not in the practice of regularly breaking news stories and subscribing to journalistic principles of neutrality and supposed objectivity.\(^ {163}\)

Finally, it is important to note that Judge Castel did not address what attorney Jeffrey D. Neuburger calls “the more difficult and complex questions concerning the use of news reports by bloggers and others who do not merely excerpt and link to online news reports such as those produced by the AP, but add commentary to them as well.”\(^ {164}\) In the opinion of the authors of this article, it would seem that legal analysis of such blogger-added-commentary situations should

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160 See supra notes 78-79 and accompanying text (describing how Judge Castel only considered the issues of choice of law, preemption and the viability of the hot news misappropriation theory under New York law).


164 Neuburger, supra note 145.
incorporate and borrow fair-use factors from copyright law. In particular, 17 U.S.C. § 107 specifically notes that criticism and comment of an otherwise copyrighted work may be protected. In fact, such commentary might even be considered a form of “news reporting” protected as a fair use. If the blogger is not making a commercial profit—per the first fair use factor—this too would militate in favor of protecting such a use in a blogger-added-commentary situation. In addition, the smaller the portion of the original article that is appropriated for purpose of commentary, the better for the blogger, as the fair-use statute asks courts to factor in “the amount and substantiality of the portion used in relation to the copyrighted work as a whole.” This issue, of course, remains unresolved, and the article now turns to the Conclusion to offer some ideas of future research and to summarize some of its own findings.

IV. Conclusion

This article has attempted to illustrate the origin, evolution, and continuing viability of the hot news misappropriation doctrine nearly a century after it was first developed and at a time when we are, as one communication scholar recently put it, “in the midst of an epochal transformation of the news media.” While the news media and the very nature of journalism may be changing today, the principles of unfair competition and reap/sow equity that gave rise in International News Service v. Associated Press to the hot news misappropriation remain vital, despite the scholarly criticism of them reviewed earlier in this article.

The AP’s lawsuit against AHN was not the first time in recent years the venerable news service has sued a business for allegedly ripping off its content, but it was the first time this century that the AP has coaxed a very favorable judicial ruling to use as precedent in

166 Id.
167 Id.
168 See id. § 107(1) (2006) (providing that courts should consider, when making a fair-use determination, “the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes”).
169 Id. § 107(3) (2006).
170 Schudson, supra note 159, at 369.
171 See supra notes 109-23 and accompanying text (providing the commentary of other legal scholars on the high court’s decision in International News Service).
other cases in which it invokes the hot news misappropriation doctrine in New York. The Associated Press thus may also consider itself fortunate that it is headquartered in New York City,\textsuperscript{173} within a jurisdiction that recognizes the hot news misappropriation tort, such that it can haul defendants into, quite literally, its home court within the Second Circuit.\textsuperscript{174} Significantly, another state with a large concentration of media entities—California—also recognizes the hot news misappropriation doctrine and recently has applied it to images, not simply news stories, in a case involving celebrity gossip-monger Perez Hilton.\textsuperscript{175} The fact that both New York and California recognize the hot news misappropriation tort brings increased power to the media companies headquartered there to fight back against nefarious competitors.

AHN’s alleged conduct of stripping AP’s stories of attribution and having them masquerade as AHN’s own work raises perhaps as many worthy ethical issues—business ethics and journalism ethics—as legal ones, but they are beyond the scope of this law-focused article. It is worth noting here, however, that the term plagiarism—a cardinal sin in journalism ethics\textsuperscript{176}—is derived from the Latin word for kidnapper,\textsuperscript{177} and that moniker perhaps provides an apt way of viewing AHN’s conduct that, in turn, tees up media ethics issues. Given that there are even ambiguities about what constitutes plagiarism in journalism, as University of Florida Professor Norman Lewis recently pointed out in a detailed study,\textsuperscript{178} there may even be a fundamental issue of whether what AHN allegedly did with the AP’s stories even constitutes plagiarism. Future articles should address the ethical aspects of AHN’s conduct and that of similar entities and news aggregators.

The news business, of course, is highly competitive. There have been lawsuits filed over the alleged stealing of sources,\textsuperscript{179} much

\textsuperscript{173} See Associated Press, Contact AP, http://www.ap.org/pages/contact/contact/contact.html (last visited Sept. 1, 2009) (identifying the AP’s headquarters as being located at 450 W. 33rd St. in New York, NY).

\textsuperscript{174} A discussion of the jurisdictional issues and choice-of-law issues is beyond the scope of this article.

\textsuperscript{175} See X17, Inc. v. Lavandeira, 563 F. Supp. 2d 1102, 1107 (C.D. Cal. 2007) (involving a case about the use of photographs by Mario Lavandeira, who does business under the name Perez Hilton, and holding that “the hot news tort is cognizable in California”).

\textsuperscript{176} See supra note 157 and accompanying text (discussing plagiarism and journalism ethics).

\textsuperscript{177} White, supra note 157, at 267.

\textsuperscript{178} Lewis, supra note 157, at 355.

\textsuperscript{179} See Kathryn S. Wenner, It’s My Source and I’ll Sue If I Want To, AM. JOURNALISM REV., Oct 2001, at 16, 16. (describing a lawsuit filed in California
less the stealing of news stories. Thus, it is not surprising that the hot news doctrine would be used today, more than ninety years after it was created, and that other news entities beyond the AP would invoke it.

For instance, the doctrine was at the heart of a dispute in 2009 between the *Scranton Times* and the *Times Leader*, rival newspapers in Northeastern Pennsylvania, in *Scranton Times v. Wilkes-Barre Publishing Co.* The dispute did not exactly involve what one might typically consider to be news; it focused, instead, on the allegation that the print edition of one newspaper was copying from the various websites of the other newspaper’s obituaries. United States District Judge A. Richard Caputo did not reject the possible existence of a hot news misappropriation claim within Pennsylvania and the U.S. Court of Appeals for the Third Circuit, but he did find that, on the specific facts of the case, the claim was preempted by federal copyright law because “the Defendant’s alleged copying and re-use of obituaries originally found in Plaintiffs’ publications did not pose a threat to the existence of Plaintiffs’ publications or the ability of those publications to continue the timely publication of obituaries.”

But future battles are more likely to occur in scenarios like those involving the Associated Press and All Headline News Corporation. When a court finally addresses the actual merits of such a case on the five specific elements of the hot news misappropriation doctrine, it will trigger an opinion meriting a further scholarly analysis. For now, as this article has illustrated, the tort that exists (at least in New York) is quite narrowly articulated and seems unlikely to quash the work of bloggers and citizen journalists in situations where they might be sued by the Associated Press.

Finally, it seems that one important issue that must be resolved in such a future case, heard on the merits, is determining for exactly how long news actually remains “hot” or “fresh” in a world of instantaneous, digital communication. When, in other words, does news become cold? As our social expectations of faster and quicker news delivery change due to technology, does this mean that a concomitantly briefer period of quasi property ownership, per a 91-year-old case, should be allowed under the hot news misappropriation tort? Although one attorney recently proposed a very precise formula for such situations under copyright law (rather than the common law hot news misappropriation tort at issue in *International News* involving competing journals that cover the wood and pulp industries and centering on the claim that the sources used by one of the journals were its trade secrets and could not be used by its former employees who went to work for the rival publication).

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181 Id. at **1-2.
182 Id. at **12-14.
it would seem this is indeed an area that requires the flexibility in equity that gives judges discretion when deciding whether to enjoin the likes of AHN for its alleged news piracy.

\footnote{See Ryan T. Holte, Restricting Fair Use to Save the News: A Proposed Change in Copyright Law to Bring More Profit to News Reporting, 13 J. TECH. L. & POL’Y 1, 3 (2008) (proposing “a change to current copyright law to bring more profit to news reporting” that “centers around allowing journalists, and the companies they work for, to own 98% of the investigated and researched facts they uncover for twenty-four hours after the story is first published”).}
KINGSDOWN TWENTY YEARS LATER: WHAT IT TAKES TO PROVE INEQUITABLE CONDUCT IS NO CLEARER

By Lynn Tyler*
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INTRODUCTION

In 2004, the author published an article that analyzed the requirements for proving the defense of inequitable conduct to a claim of patent infringement.1 In particular, the article focused on the second element of inequitable conduct – intent to deceive – and whether it can be inferred from the failure to disclose a material or highly material reference.2 The article noted that in Kingsdown Med. Consultants Ltd. v. Hollister, Inc.,3 the Federal Circuit ruled en banc in relevant part:

We adopt the view that a finding that particular conduct amounts to “gross negligence” does not of itself justify an inference of an intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.4

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2 Id. at 270-83.
4 Id. at 876.
The court overruled Driscoll v. Cebalo, which had concluded that gross negligence would support the finding of an intent to deceive. Specifically, in Driscoll, the court had written that, “Where [the inventors and their attorneys] knew, or should have known, that the withheld reference would be material to the PTO’s consideration, their failure to disclose the reference is sufficient proof of the existence of an intent to mislead the PTO.” The court’s en banc decision in Kingsdown rejected this rule. Nonetheless, the earlier article reviewed at least four Federal Circuit decisions that appeared to have resurrected the overruled standard from Driscoll. An early case to have gone astray on this issue was Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., which inexplicably relied solely on Driscoll as support for the very proposition on which Driscoll had been overruled by Kingsdown, namely, “[I]ntent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO’s consideration of the patent application.”

It is now five years later, twenty years after the Kingsdown decision, and unfortunately the conflicting state of the case law has not improved. On the one hand, there have been several Federal Circuit decisions that have relied upon or otherwise remained true to Kingsdown by finding that the failure to disclose a material reference alone is insufficient to support a finding of an intent to deceive the PTO and, therefore, inequitable conduct. On the other hand, the

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5 Driscoll v. Cebalo, 731 F.2d 878 (Fed. Cir. 1984). See id. at 876 (rejecting the Driscoll standard).
6 Driscoll, 731 F.2d at 885.
7 Id.
8 Tyler, supra note 1, at 276-83.
10 Critikon, 120 F.3d at 1256. As shown in the earlier article, this proposition was not necessary to the decision in Critikon because Critikon “involved more than the failure to disclose a known material reference; it also involved the knowing failure to disclose that invalidity and inequitable conduct were being asserted as defenses in litigation.” Tyler, supra note 1, at 278.
earlier article has now been cited in the separate opinions of two judges of the Federal Circuit. Judge Newman appeared to agree with the article that Critikon is “bad law” because it relied on the overruled Driscoll. Judge Linn cited the article as tracing to Critikon the adoption of a simple negligence standard even lower than the gross negligence standard expressly rejected in Kingsdown. Notwithstanding its awareness of the issue, however, in the past five years the Federal Circuit has issued several more precedential opinions that continue to rely upon Critikon or its erroneous version of the standard. Some of these cases are not necessarily inconsistent with Kingsdown, while several other decisions are difficult to reconcile with the Kingsdown standard for finding an intent to deceive.

Against this background, this article will first review in more detail the post-2004 Federal Circuit cases that have followed Kingsdown and held that the intent to deceive cannot be inferred merely from the failure to disclose a known material reference. Second, the article will analyze in more detail post-2004 Federal Circuit cases that have continued to inappropriately follow Critikon or other cases upholding a finding of intent to deceive based solely on the failure to disclose a known material reference. Finally, the article will review several reasons, apart from its precedential status, that the

Holdings Corp., 448 F.3d 1309, 1322 (Fed. Cir. 2006); Purdue Pharma LP v. Endo Pharm., Inc., 438 F.3d 1123, 1134 (Fed. Cir. 2006).

12 Larson, 559 F.3d at 1344 n.1 (Linn, J., concurring) (noting that prior article traced divergence in Federal Circuit precedent on this issue to Critikon, which relied on the “should have known” standard of Driscoll, which in turn had been overruled by Kingsdown; Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1202 (Fed. Cir. 2006) (Newman, J., dissenting). See Kingsdown, 863 F.2d at 876; Driscoll, 731 F.2d at 885; Critikon, 120 F.3d at 1256.

13 Ferring, 437 F.3d at 1202.

14 Larson, 559 F.3d at 1344 n.1.


16 See Cargill, 476 F.3d at 1366-68; Dippin’ Dots, 476 F.3d at 1345-46; Nilssen, 504 F.3d at 1235; Pharmacia, 417 F.3d at 1373.

17 See Monsanto, 514 F.3d at 1240-42; Praxair, 543 F.3d at 1313-19; Agfa, 451 F.3d at 1378-80; Ferring, 437 F.3d at 1191-94; Bruno, 394 F.3d at 1351-55; Novo Nordisk, 424 F.3d at 1359-62.
Federal Circuit should uniformly and strictly enforce the higher Kingsdown standard for proving an intent to deceive.

I. THE GOOD: SEVERAL POST-2004 CASES HAVE STRICTLY FOLLOWED KINGSDOWN.

The first post-2004 decision that followed the Kingsdown standard, albeit without citing Kingsdown directly, is Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.\textsuperscript{18} Purdue alleged that Endo’s proposed generic versions of OxyContin, a painkiller, would infringe three Purdue patents.\textsuperscript{19} The specification of each of the patents-in-suit included language to the effect that, using a four-fold range of dosages, the claimed oxycodone formulation achieved the same clinical results as the prior art opioid formulations achieved using an eight-fold range of dosages.\textsuperscript{20} The specification further explained that the “clinical significance” of the four-fold dosage range of the claimed oxycodone formulations was “a more efficient titration process, which is the process of adjusting a patient’s dosage to provide acceptable pain relief without unacceptable side effects.”\textsuperscript{21} Endo alleged, and the trial court found, that Purdue was guilty of inequitable conduct because it had failed to disclose that the claim about the four-fold range of dosages, compared to the eight-fold range for other opioids, was based on “insight” rather than “scientific proof.”\textsuperscript{22} Purdue appealed the inequitable conduct judgment to the Federal Circuit.\textsuperscript{23}

On appeal, Purdue did “not dispute the absence of clinical evidence during the relevant time-frame to support its claim of a four-fold dosage range for oxycodone.”\textsuperscript{24} After a lengthy discussion of materiality, the Federal Circuit affirmed the trial court’s finding that the failure to disclose the absence of experimental evidence to support the four-fold range of dosages claim was material but stressed that “[T]he level of materiality is not especially high.”\textsuperscript{25} The Federal Circuit noted that Purdue had not misrepresented that it had obtained experimental results, but “Instead Purdue made statements implying that an empirical basis existed for its discovery and then failed to disclose that the discovery was based only on insight.”\textsuperscript{26}

\textsuperscript{18} Purdue Pharma L.P. v. Endo Pharm., Inc., 438 F.3d 1123 (Fed. Cir. 2006).
\textsuperscript{19} Id. at 1125-26.
\textsuperscript{20} Id. at 1127.
\textsuperscript{21} Id.
\textsuperscript{22} Id. at 1128.
\textsuperscript{23} Id.
\textsuperscript{24} Id. at 1130.
\textsuperscript{25} Id. at 1133.
\textsuperscript{26} Id.
of intent, however, the Federal Circuit vacated the inequitable conduct judgment and remanded the case to the trial court to reconsider the evidence.\(^{27}\)

After noting that direct evidence of intent to deceive is rare and that intent to deceive can be inferred solely from the surrounding circumstances,\(^{28}\) the court went on to state, “Intent to deceive, however, cannot be ‘inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent.’”\(^{29}\) The court then quoted Critikon for the proposition that “[A] patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish ‘subjective good faith’ sufficient to prevent the drawing of an inference of intent to mislead.”\(^{30}\) The court then stated, “Nevertheless, it is important to remember that ‘materiality does not presume intent, which is a separate and essential component of inequitable conduct.’”\(^{31}\)

Turning to the facts of the case, the Federal Circuit found two errors with the trial court’s analysis of the evidence of intent to deceive. First, according to the court, the trial court improperly discounted evidence of good faith offered by Purdue.\(^{32}\) The court found that evidence that Purdue had difficulty proving its efficient titration claim related more to its attempt to obtain FDA approval for a proposed labeling claim than it did to Purdue’s attempt to obtain allowance of its patent claims and was not inconsistent with Purdue’s asserted belief that it had discovered its oxycodone was effective over a four-fold dosage range.\(^{33}\) Second, the Federal Circuit held that the trial court had failed to consider properly the level of materiality.\(^{34}\) As noted above, the Federal Circuit found that the level of materiality was low and, accordingly, there was less of a basis to infer intent from materiality alone.\(^{35}\) Because of these two errors, the Federal Circuit vacated the inequitable conduct judgment and remanded to the lower court to re-weigh the evidence, with the recommendation that the trial

\(^{27}\) *Id.* at 1135.

\(^{28}\) *Id.* at 1133-34 (citing Baxter Int’l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1329 (Fed. Cir. 1998)).

\(^{29}\) *Id.* at 1134 (quoting Hebert v. Lisle Corp., 99 F.3d 1109, 1116 (Fed. Cir. 1996)).

\(^{30}\) *Id.* at 1134 (quoting Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1257 (Fed. Cir. 1997)).

\(^{31}\) *Id.* (quoting Allen Eng’g Corp. v. Bartel Indus., Inc., 299 F.3d 1336, 1352 (Fed. Cir. 2002)).

\(^{32}\) *Id.*

\(^{33}\) *Id.*

\(^{34}\) *Id.*

\(^{35}\) *Id.* at 1134-35.
court “keep in mind that when the level of materiality is relatively low, the showing of intent must be proportionately higher.”

The Purdue Pharma case was followed shortly by M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co. In M. Eagles, the patent-in-suit covered a device for removing decals from a motor vehicle. One of the defendants’ inequitable conduct allegations was based on the plaintiff’s failure to disclose during prosecution the Model 220 die grinder which had been sold for 20 years prior to the date of the application for the patent-in-suit and which included some of the elements of the proposed claims that the examiner had not been able to find in the prior art. The district court granted summary judgment of inequitable conduct, finding that the withheld Model 220 was material because it included some elements on whose absence from the prior art the examiner had relied while allowing the patent and because the plaintiff did not offer a good faith explanation for its failure to disclose the Model 220. Accordingly, as summarized by the Federal Circuit, “The issue central to the disposition of this case is whether a lack of a good faith explanation for a nondisclosure of prior art, when nondisclosure is the only evidence of intent, is sufficient to constitute clear and convincing evidence to support an inference of intent.” The court then concluded “that a failure to disclose a prior art device to the PTO, where the only evidence of intent is a lack of a good faith explanation for the non-disclosure, cannot constitute clear and convincing evidence sufficient to support a determination of culpable intent.” After again noting that “Intent need not be proven by direct evidence,” and that intent is generally inferred from the circumstances, the court stated that “There still must be a factual basis, however, for a finding of intent.” The court concluded that “When the absence of a good faith explanation is the only evidence of intent, however, that evidence alone does not constitute clear and convincing evidence warranting an inference of intent.”

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36 Id. at 1135.
38 Id. at 1336.
39 Id. at 1338.
40 Id.
41 Id. at 1341.
42 Id.
43 Id. at 1341 (citing Merck & Co. v. Danbury Pharm., Inc., 873 F.2d 1418 (Fed. Cir. 1989)).
44 Id. (citing Hebert v. Lisle Corp., 99 F.3d 1109, 1116 (Fed. Cir. 1996)).
45 Id. But see Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997) (“Intent may be inferred where a patent applicant knew,
*Atofina v. Great Lakes Chemical Corp.* is similar in its basic facts, rationale, and result to *M. Eagles*. In *Atofina*, the patent-in-suit covered a method of synthesizing difluoromethane. After a bench trial, the district court held the patent-in-suit was unenforceable because of inequitable conduct. The inequitable conduct decision was based on Atofina’s failure to disclose the full English translation of a Japanese reference, JP 51-82206, to the PTO. The district court found that JP 51-82206 was highly material because it anticipated several claims of the patent-in-suit. The district court also based its finding of deceptive intent on certain alleged misrepresentations regarding the JP 51-82206 reference.

In its opinion, the Federal Circuit reversed the district court’s finding of intent to deceive and, thus, of inequitable conduct. Consistent with *M. Eagles*, the court held:

> The issue here is whether Great Lakes proved intent by clear and convincing evidence. The district court inferred intent from the applicants’ failure to disclose the full English translation of JP 51-82206 and its alleged mischaracterizations of that reference. However, the applicant’s failure to disclose the full English translation of JP 51-82206 is not in and of itself enough to infer intent, even if the full English translation went beyond the Derwent Abstract, which is far from clear. Intent to deceive cannot be inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent.

The court then went on to analyze the three alleged mischaracterizations of JP 51-82206 and found that none of them were actual mischaracterizations. Accordingly, the only evidence of intent to deceive was the failure to disclose, which was insufficient as a matter of law.

or should have known, that withheld information would be material to the PTO’s consideration of the patent application.”).

46 *See* *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991 (Fed. Cir. 2006).
47 *Id.* at 993.
48 *Id.* at 994.
49 *Id.* at 994-95.
50 *Id.*
51 *Id.* at 995.
52 *Id.* at 1002.
53 *Id.* at 1001-02 (quoting *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed. Cir. 1996)).
54 *Id.* at 1002.
55 *Id.*
In Old Town Canoe Co. v. Confluence Holdings Corp., the district court had granted the patentee, Old Town’s, motion for judgment as a matter of law that there was insufficient evidence of inequitable conduct. The inequitable conduct charge was based on an allegation that approximately 500 canoes had been made using the patented method and sold more than one year prior to the date of the application for the patent-in-suit. Acknowledging that the alleged prior art canoes could be material, the Federal Circuit nonetheless affirmed the judgment as a matter of law of no inequitable conduct, noting that “Confluence points to no evidence of intent to deceive the PTO.” The court relied on the familiar principle that “Materiality does not presume intent, which is a separate and essential component of inequitable conduct.” The court declined Confluence’s invitation to draw an inference of intent to deceive on appeal from the alleged materiality alone and stated that Confluence’s “general argument on this record is not sufficient to enable us to conclude that the district court abused its discretion.”

In re Metoprolol Succinate Patent Litigation reversed a summary judgment of inequitable conduct entered against AstraZeneca and affiliates in a consolidated multi-district case against several defendants alleging infringement of patents covering Toprol-XL. The inequitable conduct allegations arose out of an inventorship dispute between AstraZeneca and two former employees who had left to join another company. The two companies settled the dispute by dividing certain claims out of a pending patent application, assigning them to AstraZeneca, and naming the former employees as the inventors of those claims. The inventorship dispute was never disclosed to the PTO during the prosecution of the patents-in-suit.

The district court based its summary judgment of inequitable conduct on the conclusions that the inventorship dispute was highly material and AstraZeneca had a strong incentive not to disclose the dispute to the PTO. According to the district court, if the patent

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56 Old Town Co. v. Confluence Holdings Corp., 448 F.3d 1309 (Fed. Cir. 2006).
57 Id. at 1313.
58 Id. at 1321-22.
59 Id. at 1322.
60 Id. (quoting Allen Eng’g Corp. v. Bartel Indus., Inc., 299 F.3d 1336, 1352 (Fed. Cir. 2002)).
61 Id.
63 Id.
64 Id.
65 Id. at 1014.
66 Id. at 1020.
examiner had resolved the inventorship dispute unfavorably to AstraZeneca, one of its metoprolol succinate patents would have lost its priority date and may have been rejected as anticipated by the prior art of an intervening publication of a European patent application.\(^{67}\)

The Federal Circuit, however, found that there was a genuine issue of material fact regarding AstraZeneca’s intent to deceive because:

> [T]he deposition of Astra’s in-house patent counsel indicates that he did not know of and was not concerned about the incentives identified by the district court in its but for analysis. Therefore, the record reveals a genuine factual dispute of whether Astra had an intent to deceive the US Patent & Trademark Office.\(^{68}\)

Metoprolol Succinate thus supports the statement in several cases that, while it is possible to find inequitable conduct on summary judgment, it should be rare given the inherently factual nature of the issues.\(^{69}\)

In *Scanner Technologies Corp. v. Icos Vision Systems Corp. N.V.*, \(^{70}\) the inequitable conduct defense was based on statements made in a Petition to Make Special that were alleged to be false.\(^{71}\) After a bench trial, the district court concluded that statements in a petition to make special are always material and that some of the statements were false, supporting a conclusion of intent to deceive and thus inequitable conduct.\(^{72}\)

On appeal, the Federal Circuit agreed that false statements in a successful petition to make special are material.\(^{73}\) The Federal Circuit held, “[W]e reaffirm that a false statement that succeeds in expediting the application is, as a matter of law, material for purposes of assessing the issue of inequitable conduct.”\(^{74}\) The court began its analysis of whether the statements were false by citing *Akron Polymer Container Corp. v. Exxel Container, Inc.*\(^{75}\) for the following rule:

Whenever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a

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\(^{67}\) Id.

\(^{68}\) Id. at 1021.


\(^{71}\) Id. at 1372.

\(^{72}\) Id.

\(^{73}\) Id. at 1375.

\(^{74}\) Id.

\(^{75}\) Id. at 1376 (citing *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380 (Fed. Cir. 1998)).
district court clearly errs in overlooking one inference in favor of another equally reasonable inference. All reasonable inferences must be drawn from the evidence, and a judgment then rendered on the evidence as informed by the range of reasonable inferences. Where the rule is breached, no inequitable conduct may be found. The rule is necessary, for without it findings of inequitable conduct, with the punishment of unenforceability of the entire patent, could wrongly stand.\footnote{Id. (footnotes omitted).}

The court then reviewed in considerable detail the evidence concerning several statements from the Petition to Make Special that were allegedly false, found the evidence equivocal, and concluded that the evidence did not meet the clear and convincing standard applicable to inequitable conduct.\footnote{Id. at 1376-78.} Although Scanner Technologies did not address the intent to deceive issue, which the court found to be moot,\footnote{Id. at 1379.} it is noteworthy for its discussion of the rule of Akron Polymer, which did turn on the intent to deceive issue.\footnote{See id. at 1375; Akron Polymer, 148 F.3d at 1382.} The Akron Polymer rule is consistent with Kingsdown in its insistence on clear and convincing evidence of a high standard for intent to deceive.

\textit{Eisai Co. v. Dr. Reddy’s Laboratories, Ltd.,}\footnote{Eisai Co. v. Dr. Reddy’s Labs., Ltd., 533 F.3d 1353 (Fed. Cir. 2008).} a relatively recent decision that quoted the Kingsdown standard for finding an intent to deceive, noted that “Gross negligence is not sufficient,” and commented that “This is a high bar.”\footnote{Id. at 1360.} Eisai sued Dr. Reddy’s for infringing a patent covering rabeprazole, part of a class of drugs that suppresses stomach acid.\footnote{Id. at 1355-56.} Dr. Reddy’s and another defendant alleged five grounds for inequitable conduct: (1) the failure to disclose a co-pending application claiming the “ethyl homolog” of rabeprazole; (2) withholding rejections from the prosecution of the co-pending application that would have also been applicable to the prosecution of the patent-in-suit; (3) failing to disclose a particular prior patent; (4) submitting an allegedly misleading declaration, and (5) concealing a patent application for a prior compound in the same class of drugs.\footnote{Id. at 1360.} The district court rejected the last assertion on summary judgment and the other four after a bench trial.\footnote{Id.}
In its opinion, the Federal Circuit likewise rejected each of the five alleged grounds for inequitable conduct.\textsuperscript{85} For present purposes, the fourth ground, the allegedly misleading declaration, is most significant. The declaration was submitted to overcome an obviousness rejection and Dr. Reddy’s argued that it was misleading in part because it did not include data comparing the patented compound to the ethyl homolog.\textsuperscript{86} Although the Federal Circuit found the declaration itself highly material, it found that the materiality of the ethyl homolog was low and in any event it found no separate evidence of an intent to deceive.\textsuperscript{87} In other words, the high materiality of the declaration itself, and the low materiality of the omitted compound were not sufficient to support an inference of intent to deceive and there was no other evidence of intent to deceive, dooming the inequitable conduct allegation.\textsuperscript{88} The other allegations based on a failure to disclose were doomed for the same reasons, \textit{i.e.}, their materiality, if any, was low and there was no independent evidence of an intent to deceive.\textsuperscript{89}

The final two cases to be discussed contain some of the strongest language supporting Kingsdown’s high standard for proving intent to deceive and also the strongest actual applications of the standard. In \textit{Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.},\textsuperscript{90} the patents-in-suit covered methods of curing tobacco designed to lower the levels of tobacco specific nitrosamines (“TSNAs”) – carcinogens – in the cured tobacco.\textsuperscript{91} Star hired a patent attorney to file an application on its curing method in August 1998.\textsuperscript{92} Later that same month, Star’s attorney received a letter from a scientist and Star consultant suggesting that the prior art technique was responsible for producing cured tobacco with low levels of TSNA in China.\textsuperscript{93} A provisional application was filed in September 1998 and one year later a utility application was filed.\textsuperscript{94} Shortly after the utility application was filed, Star decided to change its prosecution counsel from one firm to another and the transfer from the first to the second was handled by yet another firm.\textsuperscript{95} The change of counsel and method of transferring the file led to the theory of inequitable conduct, namely,

\begin{itemize}
  \item \textsuperscript{85} \textit{Id.} at 1360-62.
  \item \textsuperscript{86} \textit{Id.} at 1361-62.
  \item \textsuperscript{87} \textit{Id.} at 1362.
  \item \textsuperscript{88} \textit{Id.}
  \item \textsuperscript{89} \textit{Id.} at 1360-62.
  \item \textsuperscript{90} \textit{Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.}, 537 F.3d 1357 (Fed. Cir. 2008).
  \item \textsuperscript{91} \textit{Id.} at 1361.
  \item \textsuperscript{92} \textit{Id.}
  \item \textsuperscript{93} \textit{Id.} at 1361-62.
  \item \textsuperscript{94} \textit{Id.} at 1362.
  \item \textsuperscript{95} \textit{Id.} at 1363.
\end{itemize}
that the switch was made to prevent the new counsel from learning about the consultant’s August 1998 letter and to prevent the letter from being disclosed to the PTO. The district court held a bench trial and accepted this theory, declaring the patents in suit unenforceable for inequitable conduct.

On appeal, the Federal Circuit reversed, finding “that the district court clearly erred in finding that RJR had proven that . . . Star had an intent to deceive the PTO.” After reciting the elements of inequitable conduct, the court next highlighted the importance of upholding the high standards of proof for this defense:

The need to strictly enforce the burden of proof and elevated standard of proof in the inequitable conduct context is paramount because the penalty for inequitable conduct is so severe, the loss of the entire patent even where every claim clearly meets every requirement of patentability. This penalty was originally applied only in cases of “fraud on the Patent Office . . . .” Subsequent case law has broadened the doctrine to encompass misconduct less egregious than fraud . . . but the severity of the penalty has not changed, and thus courts must be vigilant in not permitting the defense to be applied too lightly. Just as it is inequitable to permit a patentee who obtained his patent through deliberate misrepresentations or omissions of material information to enforce the patent against others, it is also inequitable to strike down an entire patent where the patentee only committed minor missteps or acted with minimal culpability or in good faith. As a result, courts must ensure that an accused infringer asserting inequitable conduct has met his burden on materiality and deceptive intent with clear and convincing evidence before exercising its discretion on whether to render a patent unenforceable.

The court then emphasized that there must be separate proof of an intent to deceive; in other words, proof that material information was withheld does not alone satisfy the deceptive intent element. Acknowledging that intent to deceive can be proven by inference from circumstantial evidence, the court nonetheless cited Scanner Technologies (discussed above) for the proposition that “[T]he inference must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be the single most

96 Id. at 1367.
97 Id. at 1365.
98 Id.
99 Id. at 1365-66.
100 Id. at 1366.
reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.”

Applying these standards to the facts of the case, the Federal Circuit found that the defendants’ “quarantine” theory – that the first law firm was replaced in a manner designed to keep the new firm from learning of the consultant’s letter – was not supported by clear and convincing evidence, so the finding of intent to deceive was clearly erroneous. The court noted that Star had offered an unrelated explanation for its decision to change prosecution counsel, but the district court found that the explanation was not credible. The explanation was that a key partner had passed away and that Star’s inventor believed another attorney in the firm had performed unsatisfactorily in an unrelated prosecution. The Federal Circuit rejected the district court’s credibility finding as a basis for inequitable conduct, however:

But even if Star’s explanations are not to be believed, it remained RJR’s burden to prove its allegation regarding the reason for the [first] firm’s dismissal. RJR cannot carry its burden simply because Star failed to prove a credible alternative explanation . . . . The patentee need not offer any good faith explanation unless the accused infringer first carried his burden to prove a threshold level of intent to deceive by clear and convincing evidence. Only when the accused infringer has met this burden is it incumbent upon the patentee to rebut the evidence of deceptive intent with a good faith explanation for the alleged misconduct.

The court then noted that there was unbridgeable gap in RJR’s evidence, namely, it had no evidence that Star knew what the consultant’s letter said prior to replacing the first firm or that the letter was a reason for the change of firms. In fact, the inventor testified that he had never seen the consultant’s letter prior to his deposition in the case. The court then observed that “[N]o inference can be drawn if there is no evidence, direct or indirect, that can support the inference. RJR’s lack of any evidence at all on the crux of its theory, let alone clear and convincing evidence, demonstrates that it failed to carry its

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102 Id. at 1367-68.
103 Id. at 1368.
104 Id. (emphasis in original; citations omitted). Note that the quoted passage, like the passages from M. Eagles quoted in supra text accompanying notes 42 and 45 appears to contradict the passage from Critikon quoted in supra text accompanying note 10.
burden.” The court also noted that the second firm was given the consultant’s letter, likewise undermining the entire theory. Given the absence of any intent to deceive, the Federal Circuit reversed the finding of inequitable conduct.

The last of the post-2004 pro-Kingsdown decisions (at least as of the writing of this article), Larson Manufacturing of South Dakota v. Aluminart Products Ltd., followed Star Scientific and applied many of its key principles. In Larson, the patent-in-suit covered a storm door with a retractable screen feature. Aluminart filed a request for reexamination with the PTO. The PTO conducted the reexamination at the same time as the prosecution of a continuation application from the patent-in-suit. The re-examination concluded with some claims canceled, some confirmed, and some allowed with slight modifications. After the district court proceeding resumed, Aluminart amended its pleadings to include a counterclaim for inequitable conduct during the reexamination. Aluminart alleged that Larson had withheld three material references and the last two (of four total) office actions from the prosecution of the continuation application. The district court sided with Aluminart, finding each of the three prior art references and both office actions material. The district court found that Larson’s intent to deceive could be inferred from its failure to disclose several material references but also from its failure to provide any plausible excuse for the withholding.

The Federal Circuit gave a detailed analysis of the materiality of the three withheld prior art references and two withheld office actions, concluding that the three references were cumulative and therefore not material but that the two office actions were not cumulative and were material. The court then turned to the question of deceptive intent. Because the district court had based its finding of deceptive intent on the failure to disclose all five withheld items, three of which the Federal Circuit found were not material, and Larson’s failure to provide any explanation, the Federal Circuit vacated the district court’s finding of deceptive intent and remanded the case to the district court to determine whether Larson withheld the

105 Id.
106 Id. at 1369.
107 Id. at 1369-70.
109 Id. at 1321.
110 Id. at 1325.
111 Id.
112 Id. at 1325-26.
113 Id. at 1326.
114 Id. at 1327-39.
two office actions from the continuation application with deceptive intent.115

“[I]n the interest of judicial economy,” the court then offered “some guidance to the district court with respect to the issue of deceptive intent.”116 After stating that the district court need not accept new evidence on remand, the court stated “[M]ateriality does not presume intent, and nondisclosure, by itself, cannot satisfy the deceptive intent element.”117 The court quoted Star Scientific for the proposition that the inference of deceptive intent “must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.”118 The court emphasized that a patentee’s failure to establish a good faith explanation for having withheld material prior art is not sufficient to prove inequitable conduct, noting that “[S]o too an accused infringer cannot carry its threshold burden simply by pointing to the absence of a credible good faith explanation.”119 Indeed, the Federal Circuit went further and stated that while a district court must consider any evidence of good faith provided by the patentee, “[T]he patentee is not required to offer evidence of good faith unless the accused infringer first meets its burden to prove – by clear and convincing evidence – the threshold level of deceptive intent.”120 Judge Linn filed a concurring opinion in Larson to call attention to the same issue addressed by this article, an issue for which he concluded “[T]he time has come for the court to review . . . en banc.”121

II. THE BAD AND THE UGLY: A REVIEW OF POST-2004 CASES DEPARTING FROM KINGSDOWN TO VARYING DEGREES.

As shown in the prior section, there is an impressive list of post-2004 cases following or at least invoking the standard for inferring deceptive intent adopted in Kingsdown. Unfortunately, there is an even longer list of post-2004 cases that cite or follow the Critikon standard for inferring deceptive intent and which are therefore inconsistent with Kingsdown to varying degrees. The first of these is

115 Id. at 1339-40.
116 Id. at 1340.
117 Id. (citing, e.g., Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1366 (Fed. Cir. 2008)).
118 Id. (quoting Star Scientific, 537 F.3d at 1366).
119 Id. at 1341 (citing Star Scientific, 537 F.3d at 1368; M. Eagles Tool Warehouse Inc. v. Fisher Tooling Co., 439 F.3d 1335, 1341 (Fed. Cir. 2006)).
120 Id. (citing Star Scientific, 537 F.3d at 1368).
121 Id. at 1344 (Linn, J., concurring).
Bruno Independent Living Aids, Inc. v. Acorn Mobility Services Ltd., in which the patent-in-suit covered a stairlift, a device that allows people with impaired mobility to travel up and down stairs on a chair that travels along a rail. Acorn accused Bruno of inequitable conduct in connection with the patent-in-suit by failing to disclose to the PTO several invalidating prior art stairlifts, including one known as the Wecolator, that Bruno had disclosed to the FDA when seeking approval to sell the stairlift covered by the patent-in-suit. The district court noted that the disclosure to the FDA had occurred concurrently with the prosecution of the patent-in-suit and that Bruno had not offered a good faith explanation for failing to disclose the same information to the PTO and inferred from those facts that Bruno had withheld the information with deceptive intent.

The Federal Circuit affirmed the district court’s finding of inequitable conduct and that the case was exceptional, warranting an award of attorneys’ fees. The court stated that “[I]n the absence of a credible explanation, intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information.” The court then went on to state that “The fact that an official of Bruno, who was involved in both the FDA and PTO submissions, chose to disclose the Wecolator to the FDA, but not to the PTO, certainly supports a finding of deceptive intent to withhold the disclosure from the PTO.” In support of the ability to draw an adverse inference from the absence of a credible explanation, the court explained, “Normally, it can be expected that an innocent party will be motivated to try to present convincing reasons for its actions or inaction. That did not occur here.” As noted in the prior article, however, there can be a variety of perfectly innocent reasons that the patentee would not or could not offer a good faith explanation. First, the patentee’s good faith explanation may be privileged and the patentee may choose not to waive the privilege. In other contexts, the Federal Circuit has held that an adverse inference cannot be drawn from a patent litigant’s refusal to waive the attorney-client privilege.

123 Id. at 1350.
124 Id. at 1350-51.
125 Id. at 1355.
126 Id. at 1354 (citing Paragon Podiatry Lab., Inc. v. KLM Labs., Inc., 984 F.2d 1182, 1193 (Fed. Cir. 1993)).
127 Id.
128 Id.
129 Tyler, supra note 1, at 285-86.
130 In re Seagate Tech., L.L.C., 497 F.3d 1360, 1370 (Fed. Cir. 2007) (en banc), cert. denied, 128 S. Ct. 1445 (2008); Knorr-Bremse SystemeFuer Nutzfahrzeuge GmbH
Second, in Bruno the patent-in-suit issued in July, 1993, and the district court’s final judgment was entered in November, 2003. As the prior article noted, “In cases where years have passed between the non-disclosure of the reference and litigation, the inventor or prosecuting counsel may legitimately no longer recall the reason(s) a particular reference was not disclosed. Patent counsel may have passed away.” While it is unknown if either of these reasons applied in Bruno, nothing in the Federal Circuit’s opinion rules them out and, given that the burden of proving inequitable conduct rests on the defendant by clear and convincing evidence, it should be up to the defendant to rule them out rather than the patentee to establish them. Otherwise, the inference of intent to deceive is not the “single most reasonable inference” as required by Larson, Star Scientific and other cases reviewed above.

Pharmacia Corp. v. Parr Pharmaceuticals, Inc., although containing some unfortunate language inconsistent with Kingsdown, is actually not inconsistent with Kingsdown. After Parr filed an Abbreviated New Drug Application (“ANDA”) seeking approval to market a generic version of a glaucoma medication named Xalatan, Pharmacia filed a suit for patent infringement. Parr alleged inequitable conduct on the basis of an allegedly inaccurate or misleading declaration submitted during prosecution by Pharmacia to overcome a rejection. The declaration contrasted the decrease in intraocular pressure caused by two different compounds, one the subject of the patent and one the subject of the prior art. These statements in the declaration conflicted with an article co-authored by the declarant and with two Japanese articles cited in the declarant’s article. The district court found that the misleading statements in the declaration were highly material because they were important to overcoming a rejection. Because the declarant’s statements contradicted statements in an article he co-authored, the district court inferred deceptive intent. Accordingly, the district court declared the patent unenforceable for inequitable conduct.

v. Dana Corp., 383 F.3d 1337, 1344 (Fed. Cir. 2004) (en banc) (invoking the attorney-client privilege or work-product immunity does not give rise to an adverse inference of willful infringement).

131 Bruno, 394 F.3d at 1350-51.
132 Tyler, supra note 1, at 286.
133 Pharmacia Corp. v. Parr Pharm., Inc., 417 F.3d 1369 (Fed. Cir. 2005).
134 Id. at 1370.
135 Id. at 1371.
136 Id.
137 Id.
138 Id. at 1372.
139 Id.
The Federal Circuit affirmed the district court’s conclusion of inequitable conduct.\textsuperscript{140} Specifically, the court wrote that “Given the highly material nature of these misleading statements and the failure to submit a directly conflicting article co-authored by the declarant himself, the district court did not clearly err in inferring an intent to deceive.”\textsuperscript{141} The court cited \textit{Semiconductor Energy Laboratory Co. v. Samsung Electronics Co.}\textsuperscript{142} for the proposition that “Proof of high materiality and that the applicant knew or should have known of that materiality makes it difficult to show good faith to overcome an inference of intent to deceive.”\textsuperscript{143} Although this quotation deviates from \textit{Kingsdown} by suggesting that a known failure to disclose highly material information alone can support an inference of intent to deceive, the misleading statements in the declaration alone are sufficient to support the judgment of inequitable conduct. The Federal Circuit has held repeatedly that affirmative misstatements in a declaration are alone sufficient to establish an intent to deceive for purposes of inequitable conduct.\textsuperscript{144} Thus, the failure to disclose the declarant’s conflicting article was not necessary to the court’s decision. It is worth noting that the \textit{Pharmacia} decision was authored by Judge Rader and joined by Judge Linn, both of whom are among the staunchest advocates for the \textit{Kingsdown} standard.\textsuperscript{145}

\textit{Warner-Lambert Co. v. Teva Pharmaceuticals U.S., Inc.}\textsuperscript{146} cites \textit{Critikon} for the now infamous proposition that “[A] patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality can expect to find it difficult to
establish subjective good faith sufficient to prevent the drawing an inference of an intent to deceive.”

Ultimately, the case is not troubling, however, because the district court found that the inventors had not appreciated the materiality of the withheld information and did not find inequitable conduct. The Federal Circuit simply affirmed the district court’s decision, made after a bench trial, as not being clearly erroneous.

In *Novo Nordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp.*, Novo sued Bio-Technology General (“BTG”) for infringing a patent covering a process for producing “ripe” human growth hormone (“hGH”) protein in bacteria by using recombinant DNA techniques. BTG’s inequitable conduct defense was based on the fact that Example 1 of Novo’s patent purported to disclose test results showing that ripe hGH protein was purified from an extract of a fusion protein. It was undisputed, however, that when the original application including Example 1 was filed, the inventors had not successfully prepared hGH with the procedures described in Example 1. In fact, the Federal Circuit affirmed the district court’s findings that Novo was never able to make ripe hGH according to the method of Example 1. The district court also found, and the Federal Circuit agreed, that Novo’s failure to disclose that it had never been able to produce ripe hGH using the method of Example 1 was material. The PTO had declared an interference between Novo’s application and a BTG application, and Novo had relied on Example 1 as establishing its right to priority. Further, during prosecution of Novo’s patent, the examiner relied upon Example 1 in deciding issues of enablement and priority.

Turning to the issue of intent to deceive, the district court found that element satisfied because Novo knew or should have known the examiner would have considered important the fact that

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147 *Id.* at 1346 (quoting *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253 (Fed. Cir. 1997).
148 *Id.* at 1347.
149 *Id.*
151 *Id.* at 1349.
152 *Id.* at 1357 (A fusion protein is one produced from two genes that have been spliced (“fused”) together.).
153 *Id.*
154 *Id.* at 1360.
155 *Id.* at 1361-62.
156 *Id.* at 1360 (Indeed, the district court had noted that whether Example 1 enabled the claimed invention “was the sole focus of the interference.”).
157 *Id.*
Example 1 contained merely prophetic data when deciding the issues of enablement and priority.\(^\text{158}\) Similarly, the board determining the interference would have found Novo’s failure to produce ripe hGH according to the method of Example 1 important to the same issues.\(^\text{159}\) Again, the Federal Circuit agreed.\(^\text{160}\) On appeal, Novo attempted to argue that the inventors did not realize that using the past tense in the description of Example 1 suggested that it had actually been performed and had not told Novo’s attorney that Example 1 was prophetic.\(^\text{161}\) Thus, Novo argued that the attorneys could not be guilty of a failure to disclose. The court rejected this argument as follows:

Novo asks us to hold, on the one hand, that the failure of . . . [the] co-inventors to disclose the truth about Example 1 to Novo’s attorneys absolves them of their duty to disclose this information to the PTO or the Board, because without their attorney’s consultation, they could not have known that this information was material. At the same time, Novo asks us to hold that its counsel’s failure to disclose the truth about Example 1 to the PTO or Board is excused because the inventors failed to fully inform them of the details surrounding Example 1. As we have done in similar situations in the past, we reject the “circular logic” of this request.\(^\text{162}\)

Although the court did not really discuss the standards for inferring an intent to deceive, it affirmed a finding of intent based solely on the failure to disclose that Example 1 was prophetic. As will be seen below, a possible important factor was that the failure occurred on more than one occasion, that is, with both the PTO and the Board.\(^\text{163}\)

*Ferring B.V. v. Barr Laboratories, Inc.*\(^\text{164}\) reached the somewhat remarkable (although not unheard of) result of affirming a summary judgment of inequitable conduct based on a failure to disclose material information.\(^\text{165}\) In *Ferring*, the patent covered a solid oral dosage form of an anti-diuretic compound to prevent diuretic

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\(^{158}\) *Id.*  
\(^{159}\) *Id.*  
\(^{160}\) *Id.*  
\(^{161}\) *Id.* at 1361.  
\(^{162}\) *Id.* at 1361-62 (quoting Brassler, U.S., I.L.P. v. Stryker Sales Corp., 267 F.3d 1370, 1380 (Fed. Cir. 2001); Molins PLC v. Textron, Inc., 48 F. 3d 1172, 1178 (Fed. Cir. 1995)).  
\(^{163}\) There is at least one other Federal Circuit decision where the court concluded that an unfortunate choice of verb tense in the description of an experiment could potentially support a finding of inequitable conduct. See Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1363-67 (Fed. Cir. 2003).  
\(^{164}\) *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181 (Fed. Cir. 2006).  
\(^{165}\) *Id.* at 1183.
symptoms associated with diabetes. After the application for the patent was filed, one of the inventors and his counsel appeared at a preliminary interview with the examiners. The examiners were concerned that a prior art patent’s disclosure of a “peroral” application of the same compound suggested oral administration of the compound for gastrointestinal absorption, just like the claimed solid oral dosage form sought to patented. The inventor argued that “peroral” referred to absorption through the walls of the mouth, not gastrointestinal absorption, and the examiner suggested that the applicants obtain evidence from a non-inventor to support that interpretation. The applicants later supplied declarations from non-inventors, but failed to disclose various connections between the inventors and Ferring. As summarized by the Federal Circuit, “[F]our of the five declarations submitted to the PTO in 1990 were written by scientists who had been employed or had received research funds from Ferring . . . .” The district court found that the failure to disclose the financial connections between the declarants and Ferring amounted to inequitable conduct. According to the district court, “[I]t must have been clear to [the inventor] at the preliminary meeting with the inventor that a non-inventor affidavit was sought for purposes of obtaining objective evidence that the invention was not anticipated by the prior art or obvious.” Thus the failure to disclose the financial connection between the declarants and Ferring was highly material and “[T]hat three of the challenged declarations were submitted after several iterations of rejected attempts to obtain the patent’s issuance speaks loudly as to motive and intent.”

The Federal Circuit first found that the declarations were highly material, noting that the “[G]eneral law of evidence has long recognized that the testimony of any witness may be rendered suspect by a past relationship with a party.” On the issue of intent, the Federal Circuit first noted that “Materiality does not presume intent, which is a separate and essential component of inequitable conduct.” Shortly thereafter, however, the court quoted Critikon for the proposition that “[A] patentee facing a high level of materiality

\[166\] Id.
\[167\] Id.
\[168\] Id. at 1183-84.
\[169\] Id. at 1184-85.
\[170\] Id. at 1185.
\[171\] Id. at 1186.
\[172\] Id. (quoting district court opinion) (emphasis in original).
\[173\] Id. (quoting district court opinion).
\[174\] Id. at 1187.
\[175\] Id. at 1190 (quoting GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1274 (Fed. Cir. 2001)).
and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish ‘subjective good faith’ sufficient to prevent the drawing of an inference of intent to mislead.” Over a dissent by Judge Newman, which included a citation to the earlier article and numerous contrary cases, the majority continued as follows:

Suffice it to say that we have recognized, in cases such as Paragon that summary judgment is appropriate on the issue of intent if there has been a failure to supply highly material information and if the summary judgment record establishes that (1) the applicant knew of the information; (2) the applicant knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding. The court then went on to determine that each of the three identified conditions was satisfied and affirmed the summary judgment of inequitable conduct.

In Agfa Corp. v. Creo Products, Inc., Agfa sued Creo for allegedly infringing six different patents covering an automated computer-to-plate system for making multiple printing plates. Creo’s inequitable conduct defense was based on Agfa’s failure to disclose at least three prior art systems, including one by Creo, to the PTO during prosecution. The trial court found, and the Federal Circuit agreed, that the withheld prior art was material because it created a prima facie case of unpatentability and also was inconsistent with a position taken during examination. On the issue of intent, the Federal Circuit found that the evidence of Agfa’s knowledge of the prior art, particularly the prior art Creo product, was “overwhelming.” The court then relied upon the principle that “A patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish subjective good faith sufficient to prevent the drawing of an inference of intent to mislead.” Noting that it “must defer heavily to the trial court’s credibility determinations,” the Federal

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176 Id. at 1191 (quoting Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1257 (Fed. Cir. 1997)).
177 Id.
178 Id. at 1191-94.
179 Agfa Corp. v. Creo Prods., Inc., 451 F.3d 1366 (Fed. Cir. 2006).
180 Id. at 1369.
181 Id. at 1371.
182 Id. at 1377.
183 Id. at 1378.
184 Id. (quoting GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1275 (Fed. Cir. 2001)).
185 Id. at 1379.
Circuit rejected Agfa’s arguments that its patent agents did not appreciate the materiality of the undisclosed references.\textsuperscript{186}

Although the intent section of the Agfa opinion focuses primarily on the knowing failure to disclose material prior art, the section of the opinion discussing the balance between materiality and intent to deceive provides more compelling support for the court’s decision:

\begin{quote}
The district court paints a picture of a group of engineers and patent agents who set out to design their own version of their competitors’ products by attending trade shows and reviewing literature, all the while taking notes and holding meetings to decide which features from which printing presses would work well in Agfa’s Galileo system. Those same agents then prepared and prosecuted the asserted patents, never sharing with the PTO any of the information they had compiled about the products upon which they modeled their system. The trial court thus found high levels of both materiality and intent, and did so with respect to numerous undisclosed pieces of prior art.\textsuperscript{187}
\end{quote}

Thus, while the intent section of Agfa alone may be dubious under the Kingsdown standard, there is reason to believe that the overall decision was correct. Agfa could be construed as a failure to disclose case, but in the end is consistent with the Kingsdown standard.

In Dippin’ Dots, Inc. v. Mosey,\textsuperscript{188} sales of the presumably patented product were made at the Festival Market Mall in Lexington, Kentucky, more than a year before Dippin’ Dots (“DDI”) filed its patent application.\textsuperscript{189} There was evidence that these sales were not experimental and it was undisputed that they were never disclosed to the PTO during the prosecution of the patent-in-suit.\textsuperscript{190} Not surprisingly, the defendants’ inequitable conduct was based in part on the failure to disclose these sales. The district court conducted a jury trial and ultimately concluded that the patent was unenforceable for inequitable conduct.\textsuperscript{191}

The Federal Circuit had little difficulty concluding that the failure to disclose the Festival Market sales was material because the “sales render the ‘156 patent invalid for obviousness.”\textsuperscript{192} The court

\begin{footnotes}
\item[186] Id. at 1378.
\item[187] Id. at 1379-80.
\item[188] Dippin’ Dots, Inc. v. Mosey, 476 F.3d 1337 (Fed. Cir. 2007).
\item[189] Id. at 1340.
\item[190] Id. at 1340-41.
\item[191] Id. at 1342.
\item[192] Id. at 1345.
\end{footnotes}
then noted that the intent to deceive issue was “more difficult.” The court affirmed, however, stating:

We have noted that omission of sales made before the critical date is especially problematic:

Absent explanation, the evidence of a knowing failure to disclose sales that bear all the earmarks of commercialization reasonably supports an inference that the inventor’s attorney intended to mislead the PTO. The concealment of sales information can be particularly egregious because, unlike the applicant’s failure to disclose, for example, a material patent reference, the examiner has no way of securing the information on his own.

While DDI wholly neglected to disclose the Festival Market sales to the PTO, it enthusiastically touted sales made after the critical date as evidence of the commercial appeal of its process. That combination of action and omission permits an inference of the minimum, threshold level of intent required for inequitable conduct.

The court then concluded that the district court was within its discretion “to balance the relatively weak evidence of intent together with the strong evidence that DDI’s omission was highly material” and to hold that DDI had committed inequitable conduct. Because the Federal Circuit’s decision relied not only on the failure to disclose, but also on the “action” of relying on evidence of sales when it was helpful to the prosecution, the decision is consistent with Kingsdown. It is also noteworthy that the court found that even the combination of action and failure to disclose still amounted only to “relatively weak” evidence of intent to deceive.

A mere five days after its decision in Dippin’ Dots, the Federal Circuit handed down another decision addressing inequitable conduct, Cargill, Inc. v. Canbra Foods, Ltd. Cargill sued Canbra and other defendants for infringing four patents, two of which are relevant to the inequitable conduct decision and related to a non-hydrogenated canola oil that possessed superior oxidative and fry stability. The claimed oil, designated IMC 130 by the patents, was allegedly novel because its oxidative stability as measured by Active Oxygen Method (“AOM”) was about thirty-five to forty hours. During prosecution,
the examiner initially rejected the proposed claims as anticipated by a European patent application that disclosed a canola oil with a fatty acid composition similar to that of IMC 130 on the theory that oxidative stability is based directly on fatty acid composition, so the oxidative stability of IMC 130 and the oil disclosed in the European patent application should be similar.200 In response, Cargill argued that another oil, designated IMC 129, had a similar fatty acid composition to IMC 130 yet the two oils had “strikingly different oxidative stability values.”201 Thus, Cargill argued that the European application could not be found to anticipate IMC 130 based solely on the similar fatty acid composition.

The Cargill defendants’ inequitable conduct allegations were based on Cargill’s failure to disclose two documents: a report containing test data indicating that three samples of IMC 129 had oxidative stabilities in a range similar to and, in one instance, actually overlapping that of IMC 130; and data showing that the oxidative stability of IMC 129 appeared to be superior to that of IMC 130 using a different, but accepted, measure.203 In light of the prosecution history in which Cargill represented that IMC 129 and IMC 130 had different oxidated stabilities notwithstanding their similar fatty acid composition, the district court found and the Federal Circuit agreed that the two documents were material.

On the deceptive intent issue, the district court found the element was satisfied based on three circumstantial factors – the repeated nature of the omission, the applicant’s motive to conceal the data inconsistent with its argument, and the high materiality of the undisclosed data.205 The Federal Circuit found that the combination of these three factors was sufficient to support a finding of the intent to deceive.206 As to the repeated nature of the omission, the court stated that it was relevant “because intent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO’s consideration of the patent application.”207 The court noted that “[E]ach of the examiners’ five rejections involved the issue of whether the oxidative stability of IMC 130 was superior to that of oil with a similar fatty acid

200 Id.
201 Id. at 1362-63.
202 Id. at 1363.
203 Id. at 1365.
204 Id. at 1365-66.
205 Id. at 1366.
206 Id. at 1366-68.
207 Id. at 1366 (quoting Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1366 (Fed. Cir. 1997)) (internal quotations omitted).
composition."\textsuperscript{208} The court also noted that Cargill’s motive to conceal referred to more than just “some general desire to obtain a patent.”\textsuperscript{209} Rather, there was a “specific motive to conceal the two specific documents at issue,” because they precluded any effort to portray IMC 130 as more than an incremental improvement.\textsuperscript{210}

Although the Federal Circuit relied almost exclusively on \textit{Critikon} in its discussion of intent, the two additional factors – the repeated nature of the omission and the specific motive to conceal the two documents at issue – make \textit{Cargill} consistent with the \textit{Kingsdown} standard. Common sense supports the conclusion that when an applicant withholds information that is inconsistent with its response to \textit{five} separate rejections, the applicant is doing so intentionally to deceive the PTO. Each time the same issue is raised, it is more and more likely that the decision to withhold the undisclosed information is intentional and less and less likely that the information is withheld through mere oversight. Further, \textit{Cargill} could also be viewed as an affirmative misrepresentation case since Cargill had argued that IMC 129 and IMC 130 oils had “strikingly different oxidative stability values” when Cargill’s own files contained evidence to the contrary.\textsuperscript{211}

In \textit{McKesson Information Solutions, Inc. v. Bridge Medical, Inc.},\textsuperscript{212} the patent-in-suit covered a patient identification system for “relating items with patients and insuring that an identified item corresponds to an identified patient.”\textsuperscript{213} The patent-in-suit was related to another patent prosecuted by the same attorney at the same time before a different examiner.\textsuperscript{214} Although the co-pending application was disclosed, the allegations of inequitable conduct arose out of the attorney’s failure to disclose the application of the patent-in-suit and the existence of a particularly relevant prior patent cited in the co-pending application, rejections issued in the co-pending application, and allowance of the claims in another related application.\textsuperscript{215}

Although it probably would not have mattered to the outcome of the case, the opinion is not entirely clear on the standard employed to prove intent to deceive. On the one hand, the court cited the express holding of \textit{Kingsdown} that gross negligence is not sufficient to establish an intent to deceive and that all of the evidence, including

\begin{footnotesize}
\begin{enumerate}
\item 208 \textit{Id.} (emphasis added).
\item 209 \textit{Id.} at 1367.
\item 210 \textit{Id.}
\item 211 See \textit{id.} at 1363.
\item 212 \textit{McKesson Info. Solutions, Inc. v. Bridge Med., Inc.}, 487 F.3d 897 (Fed. Cir. 2007).
\item 213 \textit{Id.} at 902.
\item 214 \textit{Id.} at 904.
\item 215 \textit{Id.} at 908.
\end{enumerate}
\end{footnotesize}
evidence showing good faith, must be considered.216 On the other hand, the court also wrote that “Intent to deceive cannot be inferred simply from the decision to withhold [information] where the reasons given for the withholding are plausible.”217 This quotation at least suggests that when a defendant produces evidence that material information was knowingly withheld, the patentee has some burden to provide reasons for having done so. As noted in Section I, evidence of the failure to disclose material information alone should not warrant an inference of intent to deceive and therefore should not place any burden to produce evidence on the patentee.218 Further, the McKesson court discussed Critikon, but only in the context of rebutting McKesson’s attempt to distinguish Critikon.219 In any event, the court’s incredibly thorough review of the evidence, filling approximately eighteen pages in the Federal Reporter, shows that the case is consistent with the Kingsdown standard, although reasonable minds could differ (as Judge Newman did in dissent).

In Nilssen v. Osram Sylvania, Inc.,220 an inventor attempted to navigate the prosecution process pro se with unfortunate results.221 Nilssen sued Osram Sylvania on fifteen different patents related to fluorescent light bulbs, although four were withdrawn shortly before the six-day bench trial on inequitable conduct.222 The district court found all the patents unenforceable on one or more of several grounds, including (i) submission of an affidavit in support of patentability that failed to disclose the affiant’s personal and professional association with Nilssen and financial interests in Nilssen’s patents, (ii) improper failure to pay large entity and maintenance fees, (iii) intentionally misclaiming an effective priority date, (iv) failure to disclose ongoing litigation, and (v) knowing failure to identify relevant prior art.223 With respect solely to Nilssen’s failure to disclose certain prior art, the Federal Circuit did not cite any authority discussing the standard for establishing an intent to deceive.224 The court affirmed the district court on this issue, however, writing:

The fact that Nilssen had repeatedly cited or had cited to him the prior art references in question makes it highly likely that a reasonable examiner would have wanted to

216 Id. at 913.
217 Id. (quoting Dayco Prod., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1367 (Fed. Cir. 2003)).
218 See supra notes 37-45, 107-120 and accompanying text.
219 See McKesson, 487 F.3d at 918-19.
220 Nilssen v. Osram Sylvania, Inc., 504 F.3d 1223 (Fed. Cir. 2007).
221 See id. at 1235.
222 Id. at 1226-27.
223 Id. at 1227-28.
224 Id. at 1234-35.
consider the information in the withheld patents in determining patentability. Given that these material references were repeatedly before Nilssen, and his failure to offer any good faith explanation for withholding them other than mere oversight, we find an inference that Nilssen intended to deceive the PTO not unreasonable. In other words, this case is consistent with the Cargill case discussed above where the repeated failure to disclose material information was held to support the conclusion of an intent to deceive and thus inequitable conduct. Again, it comports with common sense to infer from a repeated failure to disclose material information that the failure is intentional. In this connection, the court noted that Nilssen did offer defenses to each of the charges of inequitable conduct, which “were not per se unreasonable when considered in isolation.” The court nonetheless affirmed each of the findings, and the ultimate conclusion, noting:

However, this case presents a collection of such problems, which the district court evaluated thoroughly and considered, including making credibility findings, and it concluded that the record and testimony indicated repeated attempts to avoid playing fair and square with the patent system. Mistakes do happen, but inadvertence can carry an applicant only so far.

In other words, the court agrees that each separate failure to disclose material information (or other ground of inequitable conduct) makes it more likely that the applicant was acting intentionally or, in other words, less likely that the applicant was acting inadvertently.

Monsanto Co. v. Bayer Bioscience N.V. began as a declaratory judgment action by Monsanto challenging the validity and enforceability of four Bayer patents related to transgenic corn. More specifically, Bayer’s patent related to plants that expressed a shortened form of a protein that is toxic to certain insects. During prosecution, Bayer disclosed a prior art abstract from a presentation at a scientific conference, which noted, among other things, that the second half of the relevant protein was dispensable for producing an active insecticide. In an office action, the examiner rejected all of the pending claims as obvious over various prior art references,
including the abstract.²³² Bayer responded in part by pointing out some of the shortcomings or deficiencies of the abstract.²³³ Bayer did not disclose, however, that one of its scientists had attended the conference and taken detailed notes on a poster to which the abstract related.²³⁴ In her deposition, the Bayer scientist “carefully and extensively described the content of her handwritten notes” which showed that “The poster contained much more information than the abstract itself.”²³⁵ In her deposition testimony, the scientist “was clearly and articulately able to describe the contents of the Barnes poster as detailed in the notes.”²³⁶ Worse yet for Bayer, the scientist’s notes were “widely circulated” among relevant scientists at Bayer, including one who was responsible for prosecution of the patents at issue and admitted that he had seen the notes during prosecution of the patent-in-suit and spoken about them with the scientist who had taken them.²³⁷ The district court found that the failure to disclose the scientist’s notes was highly material because they contradicted Bayer’s arguments and established a prima facie case of unpatentability.²³⁸ Based on the failure to disclose this highly material reference, the district court also found the intent to deceive or mislead the examiner.²³⁹ Finally, the district court also found that Bayer had made a false or affirmative misrepresentation when it told the examiner that its invention had solved the problem of the unpredictability of expression of foreign genes in plants.²⁴⁰

When analyzing the intent to deceive issue, the Federal Circuit began by noting correctly that “Bayer’s failure to disclose the highly material [scientist’s] notes to the PTO during the prosecution of the [patent-in-suit] is not sufficient to prove inequitable conduct.”²⁴¹ Shortly thereafter, however, the court stated that it has “held that absent a credible reason for withholding the information, ‘Intent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO’s consideration of the patent application.’”²⁴² Because the Federal Circuit agreed that

²³² Id. at 1234-35.
²³³ Id. at 1235.
²³⁴ Id.
²³⁵ Id.
²³⁶ Id. at 1236.
²³⁷ Id.
²³⁸ Id. at 1236-37 (quoting Monsanto Co. v. Bayer Bioscience N.V., 2006 U.S. Dist. LEXIS 97254, at *168 (E.D. Mo. 2006) [hereinafter Monsanto I]).
²³⁹ Id. at 1237 (quoting Monsanto I, 2006 U.S. Dist. LEXIS 97254, at *168).
²⁴⁰ Id. at 1235, 1237 (citing Monsanto I, 2006 U.S. Dist. LEXIS 97254, at *168).
²⁴¹ Id. at 1240.
²⁴² Id. at 1241 (citing Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997)). See also Bruno Indep. Living Aids, Inc. v. Acorn
Bayer’s attempts to explain the failure to disclose the information were not credible, it affirmed the conclusion of inequitable conduct, expressly stating that it did not need to consider the alternative ground based on the affirmative misrepresentation.\textsuperscript{243} Thus, \textit{Monsanto} represents a clear holding that inequitable conduct can be inferred solely from the knowing failure to disclose highly material information in the absence of a credible explanation. This places it clearly in the \textit{Critikon} camp and in stark contrast to \textit{Kingsdown}, \textit{Star Scientific}, \textit{Larson} and other cases reviewed in Section I.

In \textit{Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.},\textsuperscript{244} the patent in suit was related to low molecular weight heparin, a drug used to prevent blood clotting while minimizing the possibility of hemorrhaging.\textsuperscript{245} The PTO’s first office action rejected the claims as anticipated and obvious over several references, including a particular European patent. The examiner stated that the references taught heparin mixtures within the molecular weight range of the claims and therefore the applicant would have to demonstrate that the claimed product provided some unexpected or unobvious property not included in the prior products.\textsuperscript{246} In response, Aventis relied on Example 6 of the patent as showing that its claimed compound had a significantly longer half-life than the formulations of the European patent on which the examiner had relied and that this difference in half-life was evidence of a difference in structure.\textsuperscript{247} The examiner was not convinced and issued a final rejection,\textsuperscript{248} leading Aventis to amend the claim and also submit a declaration from a non-inventor scientist arguing that the claimed formulation had a much longer half-life and that the longer half-life was significant because it enabled the formulation to achieve the same result at a lower dosage.\textsuperscript{249} After the examiner maintained the rejection based on the European patent, Aventis filed yet another declaration from the same scientist which provided an analysis showing a statistically significant difference between the mean half-life for the claimed compound and that of the

\begin{footnotesize}
\begin{itemize}
\item Mobility Servs., Ltd., 394 F.3d 1348, 1354 (Fed. Cir. 2005); \textit{cf.} Dayco Prod., Inc. \textit{v. Total Containment, Inc.}, 329 F.3d 1358, 1367 (Fed. Cir. 2003).
\item \textit{Monsanto}, 514 F.3d at 1241-42.
\item \textit{Aventis Pharma S.A. v. Amphastar Pharm., Inc.}, 525 F.3d 1334, 1344 (Fed. Cir. 2008).
\item \textit{Id.} at 1337.
\item \textit{Id.}
\item \textit{Id.}
\item \textit{Id.}
\item \textit{Id.} at 1339.
\end{itemize}
\end{footnotesize}
European patent and also presented additional argument. The examiner then relented and allowed the patent.

Amphastar’s inequitable conduct defense was based on the allegation that the scientist failed to disclose that the half-life studies comparing the claimed compound to the compound of the European patent were made at different doses. The district court granted summary judgment in favor of Amphastar on this defense, finding that the materiality of the half-life representations was established by the fact that Aventis referred to the improved half-life at least four times during prosecution and that the claims were allowed following the representation that the difference in mean half-life was statistically significant. The district court inferred Aventis’ intent to deceive because it “could find no credible explanation for comparing half-lives at different doses and because comparisons at the same dose showed little difference in half-life.” In an earlier opinion, the Federal Circuit found it was error to enter summary judgment on the intent to deceive issue and remanded the case for trial. At the trial, Aventis presented three explanations for the failure to disclose the dose of the European patent composition in the half-life comparisons, all of which were rejected by the district court, which again found the intent to deceive element and concluded Aventis was guilty of inequitable conduct.

In its opinion on the second appeal, the Federal Circuit considered in some detail additional arguments by Aventis seeking to overturn the finding of an intent to deceive, including at least one justification offered the first time on the second appeal. Not only did the court reject all these proposed explanations, but one gets the impression from reading the opinion that the number of different justifications, combined with the fact at least one was new on the second appeal, may have served to undermine Aventis’ credibility. Thus, the decision could be read to support the proposition that the failure to disclose highly material information, in the absence of a credible good faith explanation, supports the finding of inequitable conduct.

250 Id. at 1339-40.
251 Id. at 1340.
252 Id. at 1341 (citing Aventis Pharma S.A. v. Amphastar Pharms., Inc., 390 F. Supp. 2d 936, 941-44 (C.D. Cal. 2005) [hereinafter, Aventis I]).
253 Id. (citing Aventis I, 390 F. Supp. at 950-51).
254 Id.
256 Aventis, 525 F.3d at 1342-43.
257 Id. at 1344-49.
258 It is not unlike the murder defendant whose position is, “I wasn’t there, but if I was, I didn’t do it, and if I did, it was self-defense.”
conduct, which would be consistent with Critikon and inconsistent with Kingsdown. There is one passage in the opinion, however, where the court notes that, in the alternative, if “half-life data at other doses for the patented compound were provided to the examiner, the data were provided in a very misleading way.” This passage could make the decision consistent with Kingsdown, but such a reading of the case is strained given that the passage appears as an alternative ground for rejecting one of Aventis’ many arguments. It is more accurate to say, as Judge Rader did in his dissent, that the case merged “intent and materiality at levels far below the Kingsdown rule.”

Praxair, Inc. v. ATMI, Inc. is the most recent case (as of the writing of this article) that falls squarely within the Critikon camp. Praxair filed suit against ATMI for infringing three patents that related to “pressurized storage containers that limit potentially rapid accidental discharges of hazardous gasses [sic] that could otherwise pose a serious threat to health and safety.” More specifically, two of the patents (the “115 patent” and “609 patent”) related to flow restrictors comprised of multiple capillary passages in the path through which the gas is dispensed. ATMI based its inequitable conduct allegations against these two patents on Praxair’s failure to disclose several pieces of prior art, including restricted flow orifice (“RFO”) devices. An RFO “is a flow restrictor device presenting small holes, as small as 0.1 millimeters . . . through which gas flows.” The district court found that the failure to disclose the RFO devices was material because their use in the prior art was inconsistent with four statements made in the prosecution history of the “115 patent characterizing the prior art.” The district court found that the inventors of both the 609 and 115 patents and their counsel knew about RFO devices, which were widely used prior to the time the applications for the 115 and 609 patents were filed. Based on the failure of the inventors and their attorneys to disclose material prior art of which they were aware, and the failure to offer an explanation, the district court inferred an intent to deceived and declared both patents unenforceable for inequitable conduct.

259 Aventis, 525 F.3d at 1349.
260 Id. at 1350.
261 Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306 (Fed. Cir. 2008).
262 Id. at 1310.
263 Id.
265 Praxair, 543 F.3d at 1312.
266 Id.
267 Id. at 1312-13.
In the section of its opinion on the standards for inequitable conduct, the Federal Circuit cited Ferring and Critikon in support of the proposition that “An inference of intent to deceive is generally appropriate, however, when (1) highly material information is withheld; (2) ‘the applicant knew of the information [and] . . . knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding.”268 In the section of its opinion on intent to deceive, the Federal Circuit analyzed each of these three elements, affirmed the district court’s conclusions on each of them, and affirmed the district court’s ultimate conclusion of inequitable conduct for the 115 patent. As to the high degree of materiality, the court again noted that the RFO devices were inconsistent with four statements that were made during the prosecution of the 115 patent and that this inconsistency made the RFOs highly material.269 The court quoted testimony from both an inventor and the prosecuting attorney establishing that they were aware of the RFO devices at the relevant time.270 Finally, the court noted that Praxair had not offered a good faith explanation for its failure to disclose the RFOs but rather offered only conclusory testimony from the prosecuting attorney that he had never intentionally misled the PTO.271 The court determined that the conclusory testimony was not entitled to any weight and that what was necessary was testimony establishing the reason for the non-disclosure as of the relevant time.272 The court reached a different conclusion as to the 609 patent, however, because it had already been allowed at the time the four statements were made during the prosecution of the 115 patent and thus the four statements could not have infected the prosecution of the 609 patent.273 Praxair falls squarely into the Critikon camp because intent to deceive was inferred based solely on the failure to disclose a known material reference without a good faith explanation. This is confirmed in part by Judge Lourie’s dissenting opinion in Praxair which asserted, among other things, that “[T]he district court incorrectly conflated intent with materiality. It cited no evidence of intent to deceive. Non-citation of a reference does not necessarily justify an inference of intent to deceive.”274

268 Id. at 1313-14 (quoting Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181 (Fed. Cir. 2006)).
269 Id. at 1315-16.
270 Id. at 1316.
271 Id. at 1317.
272 Id. at 1317-18.
273 Id. at 1318.
274 Id. at 1329 (Lourie, J., dissenting) (citing M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., 439 F.3d 1335, 1342-43 (Fed. Cir. 2006)).
III. The Court Should Revert to the Kingsdown Standard Either En Banc or by Rejecting the Critikon Line of Cases in Future Panel Decisions.

The Federal Circuit was created in part to revitalize and bring uniformity to patent law. On many important issues, the court has done an excellent job on this score. Some of the more recent and noteworthy opinions include Cardiac Pacemakers, In re Seagate Technology, Knorr-Bremse, and Phillips v. AWH Corp. As shown by the two previous sections, however, the same cannot be said for the standard for proving the intent to deceive element of inequitable conduct. Depending on one’s view of whether some of the cases in Section II can be reconciled with Kingsdown, there is a roughly even split of cases following the higher Kingsdown standard and cases following the lower Critikon standard. This would be troubling under any circumstances, but is even more so given that at least some, and presumably all, of the members of the court are aware of the issue. As long ago as 2006, Judge Newman’s dissent in Ferring pointed out that Critikon does not really stand for the proposition for which it has so often been cited and further rests on the dubious foundation of a case expressly overruled in Kingsdown. More recently, Judge Linn’s concurring opinion in Larson noted that Kingsdown held that “gross negligence” was not sufficient to warrant an inference of intent to deceive but that “[I]n seeming contradiction with Kingsdown, a standard even lower than ‘gross negligence’ has propagated through our case law.” Judge Linn further noted that Critikon is the source of the problem and that it had relied on a decision expressly overruled by Kingsdown.

In part because the standard for proving intent to deceive is so unclear, the parties to patent cases can and do sometimes devote enormous resources to litigating the issue. A win on inequitable conduct is no clearer.

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277 In re Seagate Tech., L.L.C., 497 F.3d 1360 (Fed. Cir. 2007).
282 Id. at 1317-18.
conduct for the defense not only ends the case, but can lead to the recovery of its attorneys’ fees if the case is declared exceptional under 35 U.S.C. § 285. There is too much at stake to ignore the issue. With the cases evenly split, the failure to pursue the defense may not be “zealous advocacy.” If the district court and Federal Circuit follow the Critikon line of cases, the proof necessary to prevail is not particularly onerous. The Federal Circuit itself has noted “the ease with which a relatively routine act of patent prosecution can be portrayed as intended to mislead or deceive.” From this perspective, to quote Justice Brandeis, “[I]t is more important that the applicable rule of law be settled than that it be settled right.” In other words, if the standard were clearer, parties could devote fewer resources to the defense because they would be able to better assess the likelihood of success or failure and litigate or settle accordingly. As things stand now, the likelihood of ultimate success on this issue cannot be determined until the composition of the Federal Circuit panel on appeal is known.

One obvious solution to this difficulty would be for the court to return to following strictly its en banc decision in Kingsdown. Indeed, Judge Rader recommended in his dissent in Aventis that “[T]his court ought to revisit occasionally its Kingsdown opinion.” He added that “Kingsdown properly made inequitable conduct a rare occurrence.” As an en banc decision, Kingsdown can only be overruled en banc; panels are obligated to follow it. Another obvious action would be for the court to take up the issue en banc again at its earliest opportunity, as Judge Linn recommended in his Larson concurrence.

Several of the post-2004 opinions have identified a number of reasons that the standard adopted in Kingsdown is correct and should be maintained. For example, as quoted above, in Star Scientific Judge Michel wrote for the court that it is important to have a high standard for inequitable conduct “because the penalty for inequitable conduct is so severe, the loss of the entire patent even where every claim clearly meets every requirement of patentability.”

286 Aventis Pharma S.A. v. Amphastar Pharm., Inc., 525 F.3d 1334, 1350 (Fed. Cir. 2008).
287 Id.
289 See Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1365 (Fed. Cir. 2008); see also Tyler, supra note 1, at 269-70 (“Because inequitable conduct
Another reason to maintain the heightened standard for finding intent to deceive adopted in *Kingsdown* is because otherwise there is a tendency for inequitable conduct to become the affirmative defense tail that wags the litigation dog. Once again, both Judges Linn and Rader have observed this tendency. In his *Larson* concurrence, Judge Linn noted that the patent-in-suit had undergone examination twice in the PTO and after both examinations the patentee had been accused of inequitable conduct for allegedly withholding material information, despite having disclosed hundreds of references. The district court case was stayed pending the second examination and when it resumed the “second inequitable conduct allegation was the sole issue at trial.” Judge Linn further noted that, following the Federal Circuit’s remand, the litigation would continue to focus on inequitable conduct “to the exclusion of the patentee’s infringement contentions.”

For his part, Judge Rader wrote:

> Although designed to facilitate USPTO examination, inequitable conduct has taken on a new life as a litigation tactic. The allegation of inequitable conduct opens new avenues of discovery; impugns the integrity of [the] patentee, its counsel, and the patent itself; excludes the prosecuting attorney from trial participation (other than as a witness); and even offers the trial court a way to dispose of a case without the rigors of claim construction and other complex patent doctrines. This court has even observed a number of cases, such as this one, that arrive on appeal solely on the basis of inequitable conduct where the trial court has apparently elected to try this issue in advance of the issues of infringement and validity.

requires ‘forfeiture of all patent rights,’ the courts should require more compelling evidence than a mere inference that the wrongful acts were intentional.” (quoting Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1574 (Fed. Cir. 1991)).

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290 *Larson*, 559 F.3d at 1343.
291 Id.
292 Id.
293 Aventis Pharma S.A. v. Amphastar Pharm., Inc., 525 F.3d 1334, 1349-50 (Fed. Cir. 2008) (Rader, J., dissenting). *See also* Tyler, *supra* note 1, at 283 (noting that inequitable conduct allegations lead “to motions to disqualify trial counsel on the grounds that he or she will be a witness”). Within the last four years, the author alone has been involved in two cases, one as a plaintiff and one as a defendant, in which separate district courts elected to try an inequitable defense first and disposed of one patent-in-suit on that basis. In light of its tendency to overwhelm other issues in a case, the inequitable conduct defense should also be kept in check through rigorous adherence to the heightened pleading requirements of Fed. R. Civ. P. 9(b), which apply to inequitable conduct. Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., L.L.C., 350 F.3d 1327, 1342-44 (Fed. Cir. 2003). Courts should be even more demanding in their requirements to plead inequitable
In addition to these problems, the inequitable conduct defense also leads to difficult and contentious attorney-client privilege issues and contributes to an overall acrimonious atmosphere in a case given that most lawyers do not appreciate being accused of fraud.\footnote{Several post-2004 decisions have also pointed out the errors in the \textit{Critikon} standard (in addition to the fact it was based on an overruled decision). First, allowing an inference of intent to deceive to be drawn based on the high materiality of the withheld reference “\textquote{cornflakes} materiality and intent in \textquote{a} manner \ldots inconsistent with the principle that \textquote{materiality does not presume intent, which is a separate and essential component of inequitable conduct}.”\footnote{See, e.g., \textit{Tyler}, supra note 1, at 286-87.} Second, allowing the inference of intent to deceive to be drawn where the patentee knew or “should have known” of the materiality of the withheld information “sets forth a simple negligence standard, lower even than the ‘gross negligence’ standard that was expressly rejected in \textit{Kingsdown}.”\footnote{\textit{Larson}, 559 F.3d at 1344 (Linn, J., concurring).} Third, allowing the inference of intent to deceive to be drawn where the patentee does not provide a good faith explanation for withholding information: effectively shifts the burden to the patentee to prove a negative: that it did not intend to deceive the PTO. But it is the \textquote{accused infringer} – not the patentee – who \textquote{must prove by clear and convincing evidence that the material conduct in light of the Supreme Court’s decisions in \textit{Bell Atl. Corp. v. Twombly}, 550 U.S. 544 (2007), and \textit{Ashcroft v. Iqbal}, 129 S. Ct. 1937 (2009). In \textit{Twombly} and \textit{Ashcroft}, the Supreme Court adopted a two-step approach for determining the adequacy of a pleading. The first step is to identify any conclusory allegations, which should be ignored. The second step is to determine whether the remaining, specific and factual, allegations state a plausible claim. A plausible claim is one that describes conduct that is more likely to be illegal than legal. \textit{See Ashcroft}, 129 S. Ct. at 1949-50; \textit{Twombly}, 550 U.S. at 555-57. In light of these cases, sufficient allegations of inequitable conduct should be required to include specific, factual allegations that make out a plausible claim that the patentee’s conduct was more likely than not to have been intentionally deceptive. The Federal Circuit’s recent decision in \textit{Exergen Corp. v. Wal-Mart Stores, Inc.}, No. 2006-1491, 2009 U.S. App. LEXIS 17311, at **27-47 (Fed. Cir. Aug. 4, 2009), very strictly applied the heightened pleading requirements of Rule 9(b) in holding proposed allegations of inequitable conduct were insufficient, even without citing \textit{Twombly} or \textit{Ashcroft}.\footnote{\textit{Larson}, 559 F.3d at 1344 (Linn, J., concurring) (quoting Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 552 (Fed. Cir. 1990)). \textit{See also Aventis}, 525 F.3d at 1350 (“\textquote{Merging intent and materiality at levels far below the \textit{Kingsdown} rule has revived the inequitable conduct tactic.}”) (Rader, J., dissenting); \textit{Praxair, Inc. v. ATMI, Inc.}, 543 F.3d 1306, 1314-15, 1329 (Fed. Cir. 2008) (“\textquote{[T]he district court incorrectly conflated intent with materiality.}”) (Lourie, J., concurring in part and dissenting in part).}\footnote{\textit{Larson}, 559 F.3d at 1344 (Linn, J., concurring).}
information was withheld with the specific intent to deceive the PTO.”\textsuperscript{297}

Further, “The patentee need not offer any good faith explanation unless the accused infringer first carried his burden to prove a \textit{threshold level} of intent to deceive by clear and convincing evidence.”\textsuperscript{298}

IV. CONCLUSION

Notwithstanding the Federal Circuit’s avowed purpose to bring uniformity to patent law, and the awareness of at least some members of the court of the issue, since 2004 the court’s decisions have continued to diverge on the proper standard for finding the intent to deceive element of inequitable conduct. This situation should be remedied by strict adherence to the \textit{Kingsdown} standard, which was adopted \textit{en banc}, in all future decisions or, if necessary, by having the court revisit the issue \textit{en banc} to confirm the \textit{Kingsdown} standard. The \textit{Kingsdown} standard is the appropriate one for several reasons. The lower standard conflates the separate issues of materiality and intent, does not require clear and convincing evidence of intent, impugns patents, patentees, and their counsel, leads to acrimonious discovery battles and motions to disqualify, subjects patent rights (important to the nation’s economy) to undue risks, and allows one affirmative defense to overwhelm other issues in a case, among other defects. Moreover, the sooner the issue is settled the better, because under the present law parties devote enormous resources to litigating this issue given that it can be dispositive, it can lead to the recovery of attorneys’ fees, both sides can cite cases supporting their position, and the outcome cannot be predicted with any reasonable degree of certainty until the identity of the Federal Circuit panel hearing the appeal is known. None of this is good, and it should be remedied.

\textsuperscript{297} Id. (citing Star Scientific, Inc. v. R. J. Reynolds Tobacco Co., 537 F.3d 1357, 1366 (Fed. Cir. 2008)).

\textsuperscript{298} Star Scientific, 537 F.3d at 1368 (emphasis added). \textit{See id.} at 1334, 1341 (Linn, J., concurring) (“So too an accused infringer cannot carry its threshold burden simply by pointing to the absence of a credible good faith explanation.”).
COMPULSORY LICENSING OF PATENTED PHARMACEUTICALS:
WHY A WTO ADMINISTRATIVE BODY SHOULD DETERMINE WHAT
CONSTITUTES A PUBLIC HEALTH CRISIS UNDER THE DOHA
DECLARATION*

By Aileen M. McGill†

ABSTRACT

In response to concerns that patent protection for pharmaceuticals negatively affected world health, the World Trade Organization (WTO) issued the Doha Declaration in 2001, allowing member nations to issue compulsory licenses for patented pharmaceuticals during a public health crisis. The terms of this declaration allow countries to determine what constitutes a public health crisis, what terms are appropriate for compulsory licenses, and what medications they should be entitled to produce.

This article argues that the Doha Declaration has not served countries most in need of inexpensive medications: least developed countries with high rates of HIV/AIDS. The terms of the Doha Declaration are too broad, allowing countries to issue compulsory licenses for medications that do not treat life-threatening illnesses, such as Viagra and Plavix. Many countries have seen a dramatic drop in Foreign Direct Investment (FDI) as a result of extensive compulsory licensing of patented pharmaceuticals, making least developed countries hesitant to invoke the terms of the Doha Declaration for fear of similar losses in FDI. To safeguard the interests of countries facing severe health crises, the WTO should establish an administrative body to determine when a country may issue compulsory licenses of patented pharmaceuticals.
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INTRODUCTION

The balance between the rights of patent holders of pharmaceuticals and public health has become a heated source of debate in the past half century. Although medications for HIV/AIDS and other deadly diseases exist, strong patent protection for pharmaceuticals has enabled drug companies who engineered these medications to price them in order to maximize profits, at high prices beyond the reach of poor people in least developed countries. “Profits over patients or patients over profits? Patents or people?” many have questioned, rebuking the greed of these behemoth pharmaceutical companies who maintain exclusive rights over lifesaving treatment.

The tension between access to medication and intellectual property protection is more complicated than these outcries profess. The cross-section of intellectual property rights and public health needs encompasses a vast array of diverse ideologies and economic incentives among developed and developing countries. Standards for intellectual property rights, including patent rights for pharmaceuticals, were established internationally through the Trade Related Aspects of Intellectual Property Rights agreement (TRIPS) adopted by the WTO following the Uruguay Round Agreements in 1994. Although some international agreements previously governed

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1 The cost for antiretroviral treatment is approximately $10,000 to $15,000 per patient per year. See Sarah Joseph, Pharmaceutical Corporations and Access to Drugs: The “Fourth Wave” of Corporate Human Rights Scrutiny, 25 HUM. RTS. Q. 426, 446-47 (2003) (discussing how Bayer’s sale of its anti-anthrax drug at a heavily discounted price ultimately led to a WTO ministerial meeting where members recognized the “deleterious effects of widespread intellectual property recognition on the ability of poor people to obtain essential drugs.”).


intellectual property protection between other countries—namely, the Berne Convention,\(^4\) the Paris Convention,\(^5\) and others—TRIPS is unique because it binds any country to its system of intellectual property protection if that country wants to participate in international trade through the WTO. Membership in the WTO requires adherence to TRIPS.\(^6\)

TRIPS supporters, primarily developed countries and drug companies, heralded it as a positive step in combating piracy, counterfeiting, and patent infringement worldwide, protecting the rights of intellectual property holders.\(^7\) Its critics are quick to note that the scope of patent protection for pharmaceuticals varied tremendously between countries prior to the adoption of TRIPS due to both theoretical perspectives of the rights inherent in intellectual creation and the health and economic circumstances within developing countries.\(^8\) The uniform standards established by TRIPS did not correspond to the ideals of many countries, and continue to create problems with nations that disagree with its terms who have sought to circumvent patent protection whenever possible.

Because of the trade advantages of WTO membership, countries with diverse social, economic, and healthcare needs have reluctantly signed on to this universal system of intellectual property rights under standards largely advocated by economic powerhouses, such as the United States, acting under lobbying pressure from drug companies.\(^9\) Patent protection under TRIPS guarantees patent holders the right to exclusive use of their medication for twenty years with no

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\(^6\) The obligations of compliance for TRIPS apply equally to all WTO member nations, though developing countries were given a buffer period to come into compliance. See TRIPS, supra note 3, art. 65; see also World Trade Organization, Overview: the TRIPS Agreement, http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Nov. 13, 2009).

\(^7\) See generally Mark A. Groombridge, The TRIPS Trade-Off: Reconciling Competing Interests in the Millennium Round, 2 J. WORLD INTELL. PROP. 991 (1999) (discussing both the successes of TRIPS and residual issues in implementation).

\(^8\) For a discussion of the ways in which initial compliance with TRIPS may impose a significant burden on developing countries, see id. at 1003-05.

limit on price. Advocates of strong patent protection argue that exclusive patent rights are necessary to incentivize research and development of medications. But are we giving patent holders more protection than they need to create incentives to produce these medications? Has intellectual property protection become a tool for abuse instead of advancement? Can we find a way to reconcile intellectual property rights with public health and humanitarian concerns?

In light of these questions and the increasing evidence that patent protection was negatively affecting world health by erecting a barrier between sick people and the medication they need, the WTO amended TRIPS in 2001 under the Doha Declaration to broaden the criteria to facilitate compulsory licensing of patented pharmaceuticals for countries facing a public health crisis. Furthermore, countries that lack domestic pharmaceutical production abilities may import these medications from countries that produce the medications for them for this purpose. Since the Doha Declaration’s passage, compulsory licensing or threats of compulsory licensing have issued from a number of countries, seeking to use the Doha Declaration’s terms to combat a variety of diseases from AIDS to Anthrax to

10 TRIPS, supra note 3, art. 28.
11 See, e.g., Vishal Gupta, A Mathematical Approach to Benefit-Detriment Analysis as a Solution to Compulsory Licensing of Pharmaceuticals Under the TRIPS Agreement, 13 CARDozo J. INT’L & COMP. L. 631, 631 (2005) (noting that “the very thing that limits access to these medicines, the right to exclude others from making, using, offering for sale or selling the invention,” is also what promotes innovation in the first place.”).
14 Brazil has been the leader in using compulsory licensing or threats of compulsory licenses to negotiate reduced prices for HIV/AIDS medications. A number of other countries including South Africa, India, and Thailand have similarly used compulsory licenses to produce generic forms of HIV/AIDS antiretroviral therapies. For a comprehensive list of countries that have issued compulsory licenses for the production of pharmaceutical products, including ARVs to treat HIV/AIDS, see JAMES PACKARD LOVE, RECENT EXAMPLES OF THE USE OF COMPULSORY LICENSES ON PATENTS, KNOWLEDGE ECOLOGY INT’L (2007), available at http://www.keionline.org/misc-docs/recent_cls.pdf.
15 In 2001, the United States threatened Bayer that it would issue compulsory licenses for the production of Ciprofloxacin, an antibiotic that treats Anthrax, if Bayer did not match the price for generic versions of the drug. The United States intended to stockpile the drug in fear of a bioterrorist attack. See Keith Bradsher, U.S. Says Bayer will Cut Cost of its Anthrax Drug, N.Y. TIMES, Oct. 24, 2001, at B7.
heart disease. Regardless of the severity of their situation, ability to pay for medications, or connection to the medication at issue, countries have declared a public health crisis in order to produce generic versions of patented formulas under the terms of the Doha Declaration.

While the goal of the WTO to increase access to medication during public health emergencies is a good one, the terms of this provision have led to unfettered discretion by nations to dictate the terms of their own compulsory licensing programs. The WTO intended, through this agreement, to ensure that countries facing public health crises that lacked the ability to pay for pharmaceuticals at patent prices, would be able to invoke these terms to ensure that their citizens had access to medication. Because member nations may dictate when they are entitled to compulsory licensing for a wide range of pharmaceutical products, however, countries have invoked compulsory licensing for a range of conditions that may go beyond the definition of a “public health crisis” the WTO intended. This unchecked discretion has created a negative association with compulsory licensing, and may be hurting the very countries needing access to life-saving medications most: least developed countries facing severe public health crises that lack domestic pharmaceutical production capacity.

This article argues that the Doha Declaration should be revised to increase checks on when countries may issue compulsory licenses for pharmaceuticals. Particularly, it argues that the discretionary terms of the Doha Declaration are hurting least developed countries that lack domestic pharmaceutical production capacity because past negative

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16 In 2007, Thailand announced it would issue a compulsory license to a domestic pharmaceutical production company to begin production of Plavix, a blood thinner that prevents heart disease. Love, supra note 14, at 13.

17 See generally id. (outlining a number of recent examples of the use of compulsory licenses, in both developed and developing economies).

18 The Doha Declaration permits countries to “grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.” Doha Declaration, supra note 12, ¶ 5(b).

19 Under the Doha Declaration paragraph 4, the WTO “affirm[ed] that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.” Id. ¶ 4.

20 Doha Declaration paragraph 5(c) gives countries the authority to determine what constitutes a public health crisis for purposes of invoking compulsory licenses. “Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.” Id. ¶ 5(c).
publicity, political repercussions, and negative economic consequences of compulsory licensing have made these countries hesitant to invoke its terms. Part I addresses different countries’ interpretations of what intellectual property rights should entail, how the globalization of intellectual property protection standards was dominated by developed countries, particularly the United States, and how this has led to backlash from countries who disagree with its terms through extensive compulsory licenses. Part II discusses the applicable agreements governing patent protection and compulsory licensing and how these terms have been used by both developed and developing countries. Giving developing countries a louder voice than they had in the formation of TRIPS in the scope of pharmaceutical patent protection is a wise goal of the WTO. However, discretionary compulsory licensing of patented pharmaceuticals is likely not the appropriate means to ensure these countries receive the medications they need or the voice in the WTO they deserve. Countries that have issued compulsory licenses widely prior to the adoption of TRIPS, under conditions that the Doha Declaration permits, have seen dramatic decreases in FDI. These negative consequences have made other countries facing health crises hesitant to import medication under compulsory licensing out of fear of similar negative economic effects. Unchecked discretion for compulsory licensing has made compulsory licenses a dirty word for economic development and erected a barrier between generic drugs and the least developed countries that need them.

In conclusion, this article proposes how decision-making by a WTO member body could prevent the abuses of the compulsory licensing program in the Doha Declaration. In this framework, the WTO, through representatives from all member nations, will act to ensure that the amendments adopted through the Doha Declaration benefit those most in need of life-saving medication.

I. COUNTRIES VIEW INTELLECTUAL PROPERTY AND THE ADOPTION OF TRIPS DIFFERENTLY.

A. THE APPROPRIATE LEVEL OF PATENT PROTECTION FOR PHARMACEUTICALS VARIES BETWEEN DEVELOPED AND DEVELOPING COUNTRIES BASED ON THEIR THEORETICAL IDEALS AND ECONOMIC NEEDS.

Countries perceive the scope of protection for intellectual property rights differently based on differing values pertaining to
public welfare and the relative importance of private property rights.\textsuperscript{21} Some countries, such as the United States, afford intellectual property holders the full panoply of rights that they give to owners of real estate or chattel: the rights to possess, improve, transfer, exclude others, and most importantly, the right to waste.\textsuperscript{22} There are no exceptions or limitations for patented pharmaceuticals, such that one who has invented a lifesaving medication no less than one who has invented a widget machine has the right to both exclude others from using that formula and choose not even to produce that medication if he chooses.\textsuperscript{23} This legal right reflects how the United States views the individual right to property ownership, even ownership in one’s ideas, as an important human right and a necessary component of our capitalist system.

The United States’ patent system uses this grant of property rights as the counterweight in the delicate balance with society’s benefits of full disclosure of those ideas and a rich public domain when patent protection expires. Granting strong, guaranteed property protection in new creations, the public receives the benefit of knowing that new developments are not kept secret in return for the inventor’s legal monopoly over the implementation of these ideas.\textsuperscript{24} Society receives the benefit of full disclosure of these ideas, which may often spawn new ideas and new creations. The full disclosure of new ideas may be the strongest benefit of patent rights; the question within any patent system arises as to what incentives are necessary to ensure that people research and develop new ideas and continue to disclose them to the public.

Other countries’ patent systems reflect an ideal in which private property rights do not play so dominant a role in their intellectual property systems. Rather, patent protection is meant not only to encourage innovation by rewarding innovators with certain


\textsuperscript{22} “No patent owner otherwise entitled to relief for infringement . . . shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having . . . (4) refused to license or use any rights to the patent.” 35 U.S.C. § 271(d) (2006). This statute authorizes a patent holder the right to bring a claim for infringement against an infringing party even if the patent holder has not used the rights of the patent. See id. This statute was part of the Patent Misuse Reform Act of 1988. Id. (originally enacted as Patent Misuse Reform Act of 1988, Pub. L. No. 100-703, 102 Stat. 4674).

\textsuperscript{23} Patentable subject matter includes pharmaceutical products and the process involved in making them. 35 U.S.C. § 101 (2006).

\textsuperscript{24} One of the requirements for patentability is full disclosure of the patent, with adequate descriptions enabling one having prior skill in the art to practice the patent. 35 U.S.C. § 112 (2006).
rights, but also to enrich the economy, provide jobs, and ensure that new and useful inventions are widely produced.\textsuperscript{25} Failure to produce the patented product, in most countries, is considered an abuse of the monopoly rights granted to the patent holder; laws in those countries provide for compulsory licensing and even revocation of the patent, in some cases, where the patent holder does not “work” the patent.\textsuperscript{26}

India is one interesting case example of a country that has interpreted patent rights very differently from the United States. In India, patent holders are required to work the invention within the country so as to establish “a new industry . . . which would profitably employ the labour and capital of the country and thus increase the national wealth.”\textsuperscript{27} As one commentator notes, “patent systems are not created in the interests of the inventor but in the interests of the national economy.”\textsuperscript{28} Under this governmental goal of granting patents only where it benefits the country, as a whole, Indian patent law explicitly prohibits the patenting of pharmaceuticals, believing that monopoly power over a medication is not in the public interest.\textsuperscript{29} Many other countries have forbidden patent protection for pharmaceuticals at some point in the twentieth century or have broad exceptions for pharmaceuticals, including Austria, Brazil, Bulgaria, Canada, Chile, the Czech Republic, Denmark, Germany, Hungary, Italy, Japan, the Netherlands, Pakistan, Poland, Spain, Sweden, and Switzerland.\textsuperscript{30} India does, however, provide a patent for the process of creating the pharmaceutical product, ensuring that its inventor may receive some exclusive rights to his process,\textsuperscript{31} though compulsory licenses for patents relating to medicines, including such process, may be obtained by an interested party.\textsuperscript{32} On the whole, India represents a broad class of countries that consider patent protection to be a tool for

\textsuperscript{25} See Narayanan, supra note 21.
\textsuperscript{26} Brazilian law, for example, requires patents to have industrial application such that the invention “can be made or used in any kind of industry.” Código de Propriedade Industrial [C.P.I.] tit. I arts. 8, 9, 15 (Braz.), translated at http://www.inpi.gov.br/menu-esquerdo/marca/dirma_legislacao/oculto/LEI9279INGLES.pdf. Likewise, a compulsory license may be granted if the patentee does not produce the patent in Brazil. Id. art. 68 § 1(I).
\textsuperscript{27} Narayanan, supra note 21, at 3.
\textsuperscript{28} Id. at 3-4 (citing 1 Aloys John Michel, The World’s Patent Laws 15 (1945)).
\textsuperscript{29} Id.
\textsuperscript{30} Id.; see also J.W. Baxter, World Patent Law and Practice 73-76 (2d ed. 1968) (discussing countries which do not provide pharmaceuticals full patent protection).
\textsuperscript{31} Narayanan, supra note 21, at 3-4 (citing 1 Aloys John Michel, The World’s Patent Laws 15 (1945)).
\textsuperscript{32} Id.
public good with decreased emphasis on personal property rights in innovation.

B. AMERICAN VIEWS OF STRONG PATENT PROTECTION FOR PHARMACEUTICALS DOMINATED TRIPS DUE TO THE LOBBYING POWER OF THE PHARMACEUTICAL INDUSTRY AND THE TRADE INFLUENCE OF THE UNITED STATES.

The United States was the strongest supporter of linking intellectual property requirements with world trade and used TRIPS to ensure that countries would be required to comply with patent protection under American ideals.\textsuperscript{33} The goal of harmonizing intellectual property protection worldwide has largely been a product of the shift in the American economic system from an industrial to a knowledge-based economy. Countries such as China, India, and other developing countries have taken over the manufacturing and industrial components of international trade.\textsuperscript{34} The United States now exports primarily entertainment, attractive brand names,\textsuperscript{35} and innovation,\textsuperscript{36} including products created by the multi-billion dollar pharmaceutical company that lobbied heavily for the passage of TRIPS.\textsuperscript{37} The United States’ economy relies on profits from innovation. Thus, the United States pushed heavily to pass a system of intellectual property protection that embodied our strong private property rights in patents and ensured its adoption worldwide by linking it to the benefits of the WTO.\textsuperscript{38}

The TRIPS agreement, as adopted, reflects the broad property rights of the American intellectual property system. In fact, the agreement parallels American law almost exactly. First, TRIPS requires a minimum term of twenty years of patent protection,\textsuperscript{39}

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\item[33] CARLOS M. CORREA, TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS; A COMMENTARY ON THE TRIPS AGREEMENT (2007).
\item[34] China, for example, dominates the world in manufacturing, producing two-thirds of the world’s copiers, microwaves, DVD players, shoes, and toys. Fareed Zakaria, \textit{Does the Future Belong to China?}, NEWSWEEK, May 9, 2009, at 28.
\item[35] See Burt Helm, \textit{Best Global Brands}, BUSINESSWEEK, Sept. 29, 2008, at 56. Four out of the five most valuable brands are American companies. These brands are Coca-Cola, IBM, Microsoft, and GE, while Nokia, a Finnish company, is the fifth most profitable. \textit{Id}.
\item[36] See id. (noting that three of America’s four most valuable international brands, IBM, Microsoft, and GE are companies known for developing new technology).
\item[37] GAIL E. EVANS, LAWMAKING UNDER THE TRADE CONSTITUTION: A STUDY IN LEGISLATING BY THE WORLD TRADE ORGANIZATION (vol. 14, 2000).
\item[38] CORREA, \textit{supra} note 33.
\item[39] TRIPS, \textit{supra} note 3, art. 33.
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similar to American law at that time\textsuperscript{40} and longer than most other countries’ patent protection prior to TRIPS.\textsuperscript{41} Second, there is no “local working” requirement for patent holders, and it does not authorize compulsory licensing if a patentee fails to work the patent locally,\textsuperscript{42} a policy directly at odds with most countries.\textsuperscript{43} The United States did not want their patented ideas to be put to use through manufacturing in other countries under compulsory licensing terms which did not maximize the profits of its drug companies.\textsuperscript{44} Local working has been a source of dispute and unrest between Brazil and the United States for some time, and is still relatively unresolved.\textsuperscript{45} Finally, TRIPS does not make exceptions for the patenting of pharmaceuticals or pharmaceutical processes, unlike the terms of India’s laws and those of many other countries.\textsuperscript{46} Pharmaceuticals receive the same patent protection as other products.\textsuperscript{47}

The terms of TRIPS favor producers of patented products, primarily developed countries, and the United States in particular, and American pharmaceutical companies.\textsuperscript{48} This outcome should not be surprising given that executives from many of the highest grossing American pharmaceutical companies were members of the U.S President’s Advisory of Committee on Trade Policy and Negotiations (ACTPN), and directly supported TRIPS.\textsuperscript{49} James R. Enyart, Director

\textsuperscript{40} Prior to TRIPS, American law gave patent holders seventeen years of protection. The law was amended in 2006 to comply with TRIPS. 35 U.S.C. § 154(a)(2) (2006).


\textsuperscript{42} TRIPS, supra note 3, art. 27, 28.

\textsuperscript{43} See NARYANAN, supra note 21 (discussing the patent laws of various countries).


\textsuperscript{46} See NARYANAN, supra note 21 (discussing the patent laws of various countries); see also Versão em Inglês [C.P.I.] tít. I art. 43 (Braz.) (providing wide exceptions for infringement relating to medical products), translated at www.inpi.gov.br/menu-esquerdo/marca/dirma_legislacao/oculto/LEI9279INGLES.pdf.


\textsuperscript{48} Wilson, supra note 9, at 264.

\textsuperscript{49} Peter Drahos, Global Property Rights in Information: The Story of TRIPs at the GATT, 13 PROMETHEUS 6, 8 (1995). See James Thou Gathii, The Structural Power
of International Affairs at Monsanto, defended the lobbying of the pharmaceutical and biotech industry and noted: “The rules of international commerce are far too important to leave up to government bureaucrats and their academic advisers. But governments, not businessmen, make rules and they only listen when the chorus gets big enough and the singing gets loud enough.” The voice of pharmaceutical companies undoubtedly has had a loud and permanent effect on international intellectual property rights.

II. THE DOHA DECLARATION HAS NOT GIVEN LEAST DEVELOPED COUNTRIES A SIGNIFICANT ROLE IN INTERNATIONAL PATENT POLICY, AND IT HAS LED COUNTRIES TO INVOKE COMPULSORY LICENSING FOR SCENARIOS THAT MAY HAVE BEEN BEYOND THE SCOPE OF THE WTO’S INTENDED USE.

A. THE WTO ISSUED THE DOHA DECLARATION TO BROADEN THE TERMS UNDER WHICH COUNTRIES MAY ISSUE COMPULSORY LICENSES, INTENDING TO FACILITATE ACCESS TO LIFESAVING MEDICATIONS IN PUBLIC HEALTH CRISIS.

Medications to treat life-threatening illnesses such as HIV/AIDS are available but pharmaceutical companies have priced them out of reach of those hardest hit by these illnesses and may continue to do so under TRIPS. HIV/AIDS has been the focus of this controversy due to its devastating toll on many least developed countries, the fact that many of its treatments are still under patent protection, and the high prices charged by pharmaceutical companies that hold these patent rights. Although treatments for other illnesses have been affected by TRIPS, this paper will use HIV/AIDS as an example to illustrate some of the consequences of reduced access to medications under patent protection.

Developing countries, particularly countries in sub-Saharan Africa, have been the hardest hit by HIV/AIDS. According to the

of Strong Pharmaceutical Patent Protection in U.S. Foreign Policy, 7 J. GENDER, RACE & JUST. 267, 268 (2003) (noting that “[s]trong patent protection is . . . the primary U.S. foreign policy position on how to facilitate access to essential medicines under patents held by U.S. and western pharmaceutical corporations.”). This policy position reflects the lobbying pressure of the pharmaceutical industry.


The cost of a year’s supply of anti-retroviral drugs in the United States far exceeds the income of the average person infected by HIV/AIDS in developing countries. Joseph, supra note 1, at 428.
United Nations, Africa “remains the most severely affected region,” with approximately twenty-two million out of thirty-three million people worldwide living with HIV at the end of 2007. Sixty-one percent of women and 90% of children living with HIV/AIDS worldwide are in sub-Saharan Africa. Furthermore, life expectancy at birth has dropped below forty years in seven African countries: Central African Republic, Lesotho, Malawi, Mozambique, Swaziland, Zambia, and Zimbabwe.

Although there is no cure for HIV/AIDS, anti-retroviral (ARV) drugs have been available since 1996, and have been shown to be very effective in improving the quality of life and prolonging life for those infected with HIV. ARV therapies, which are still under patent protection, cost between $10,000 and $15,000 per person in the United States, a price that far exceeds the reach of citizens of sub-Saharan Africa. Patent rights and the ability to price medications at these high prices, thus, have prevented citizens in developing countries from accessing such medications that could allow them to live longer, healthier lives.

In response to the AIDS crisis as well as other diseases worldwide and the patented medications available to treat them, the WTO convened in 2001 in Doha, Qatar, to draft an amendment to TRIPS. The WTO did not override the terms of TRIPS, but amended them to enable countries to access medications in a wider variety of circumstances under royalty terms that the country issuing the compulsory license may determine.

54 GLOBAL AIDS ALLIANCE, FACT SHEET: GLOBAL AIDS STATISTICS (2009), http://aidsalliance.3cdn.net/83e598ec.dabca06971_fbm6bnx9s.pdf.
56 Joseph, supra note 1, at 427.
57 Id. at 428.
58 See Doha Declaration, supra note 12. The WTO stated that they sought, through this declaration to “reiterate[e] our commitment to the TRIPS agreement” but “affirm[ed] that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health . . . .” Id. ¶ 4.
59 Id. ¶ 5(c). Under Doha Declaration paragraph 5(b), “[e]ach Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which
original TRIPS agreement allow member nations to issue compulsory licenses to third parties to satisfy local needs.\textsuperscript{60} They require, however, that compulsory licensing take place only after efforts have been made to obtain authorization from the patent holder, a requirement that can be waived “in the case of a national emergency or other circumstances of extreme emergency.”\textsuperscript{61} The Doha Declaration broadens the conditions under which member nations can issue compulsory licenses, recognizing each member nation’s “freedom to determine the grounds upon which such licenses are granted.”\textsuperscript{62} Under this provision, countries may dictate the royalties they pay to pharmaceutical companies in any situation it deems appropriate without attempting to negotiate with the patent holder prior to issuing the license.\textsuperscript{63}

One challenge the WTO encountered in drafting this amendment was ensuring that countries that lacked domestic pharmaceutical production capabilities would still be able to make use of compulsory licensing of the patented pharmaceuticals they needed. Most of the least developed countries that are unable to afford patented medications also lack a facility within its borders capable of producing generic forms of these medications. For example, about 80% of developing countries lack a functional pharmaceutical sector capable of domestic production of ARV drugs to treat HIV/AIDS.\textsuperscript{64} This dilemma, articulated in paragraph 6 of the Doha Declaration, called on “the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council.”\textsuperscript{65} The Council responded through a waiver known as the Decision of 30 August 2003 (Waiver Decision).\textsuperscript{66} This decision, adopted permanently through Article 31bis of TRIPS,\textsuperscript{67} allows countries with pharmaceutical licenses to determine the royalties they should pay to patent holders.\textsuperscript{68}

\textsuperscript{60} TRIPS, supra note 3, arts. 30-31.
\textsuperscript{61} Id. art. 31.
\textsuperscript{62} Doha Declaration. supra note 12, ¶ 5(b).
\textsuperscript{63} See Arvind Panagariya, Developing Countries at Doha: A Political Economy Analysis, in GLOBAL TRADE POLICY 9; 11 (Peter Lloyd and Chris Milner eds., 2003) (2002).
\textsuperscript{65} Doha Declaration, supra note 12, ¶ 6.
\textsuperscript{66} Implementation of Paragraph 6, supra note 13.
\textsuperscript{67} World Trade Organization General Council, Protocol Amending the TRIPS Agreement, ¶ 1, WT/L/641 (Dec. 6, 2005).
production capabilities to export generic forms of patented drugs to a
country that lacks domestic pharmaceutical production capacity under
conditions identical to those as if the importing country were to
produce the drugs themselves. 68

B. THE WTO DELIBERATELY LEFT THE DEFINITION OF
“PUBLIC HEALTH CRISIS” AND “PHARMACEUTICAL
PRODUCT” VAGUE SO AS NOT TO OBSTRUCT BARRIERS
TO UNFORESEEABLE PUBLIC HEALTH NEEDS IN TIMES
OF CRISIS.

In drafting the Doha Declaration, the WTO struggled in
defining what scope of diseases and medications should be covered by
compulsory licensing allowances. “From the outset [of the] Paragraph
6 mandate, developing countries demanded that the solution to this
problem be applied broadly to both diseases and treatments.” 69 The
United States tried to restrict its scope to HIV/AIDS, malaria,
tuberculosis, and a small group of infectious diseases.” 70 The
European Committee also “proposed that the declaration be limited to
‘grave’ public health problems,” invoking the possibility of “WTO
intervention to determine the gravity of [a] nation’s public health
crises for compulsory licensing purposes.” 71

In a move uncharacteristic of prior TRIPS negotiations,
developing countries prevailed in their push for broad, discretionary
interpretation of the scope of diseases covered by the terms of the
Doha Declaration. 72 As Abbott and Reichman note, “[t]here is no
public health justification for denying patients access to treatments for
certain diseases because trade officials have decided that some
diseases should be on (or off) an official list.” 73 Indeed, a pre-
determined list of diseases that may benefit from compulsory licensing
is not in the public’s best interest; diseases that threaten public health
mutate, evolve, and present unforeseeable degrees of gravity,
mortality, contagiousness, and treatability.

This agreement was intended to provide nations with the
discretion to determine what conditions constitute a public health

68 World Trade Organization General Council, Annex to the Protocol Amending the
TRIPS Agreement, ¶¶ 1-2, WT/L/641 (Dec. 6, 2005).
69 Frederick M. Abbott & Jerome H. Reichman, The Doha Round’s Public Health
Legacy: Strategies for the Production and Diffusion of Patented Medicines Under
70 Id.
71 Id.
72 Doha Declaration, supra note 12, ¶ 5(c).
73 Abbott & Reichman, supra note 69, at 936-37.
Paragraph 5(b) states that “[e]ach member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”75 This expansive language appears to indicate that countries can and should grant compulsory licenses under its own terms for any pharmaceutical product. However, the following paragraph states that “[e]ach member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises including those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”76 While the WTO did not limit compulsory licensing to “HIV/AIDS, tuberculosis [and] malaria” as the United States had advocated, it indicated that this declaration intended to target “epidemics” and “circumstances of extreme urgency.”77 It would be unusual for the WTO to give member nations the authority to make determinations as to a “national emergency or other circumstances of extreme urgency” if it intended for countries to issue compulsory licenses under any circumstances.78

Similarly, the scope of pharmaceuticals that may be produced in generic form under a compulsory license was deliberately left undefined in the Doha Declaration.79 Both the Waiver Decision and the pending Amendment establish broad subject matter that may be furnished under this system, encompassing any product of the pharmaceutical sector including vaccines and diagnostic kits.80 By extending the terms broadly enough to encompass existing products that do not treat life-threatening illnesses, the WTO may have signaled its intent to allow wide, discretionary use of compulsory licensing.81 However, it is more likely that the absence of a list or class of predetermined medications subject to compulsory licensing was not intended to grant discretionary usage of these terms under any circumstances. Rather, similar to its refusal to limit what diseases may constitute a national emergency, the WTO did not want to limit what

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74 See Doha Declaration, supra note 12, ¶ 5(c) (“Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises . . . can represent a national emergency or other circumstances of extreme urgency.”).
75 Id. ¶ 5(b).
76 Id. ¶ 5(c).
77 Id.
78 Id.
79 See generally id. (The Doha Declaration does not articulate a list of medications or class of medications that may be produced through compulsory licenses).
80 Abbott & Reichman, supra note 69, at 937.
81 See id. (“Paragraph 1 of the Doha Declaration does not contain any limitation on the application of the Declaration to specific diseases or medicines.”).
treatments should be available to combat such a crisis. The availability of vaccines and diagnostic kits may be a valuable asset during a national health emergency; indeed, vaccines have been used by governments, including the United States, to prevent the spread of a contagious disease.

Developing countries prevailed on both accounts, in leaving the scope of diseases and pharmaceutical products unlimited in the Doha Declaration. However, this ambiguity has not led to extensive benefits for least developed countries facing the most severe health crises, specifically sub-Saharan African countries suffering from HIV/AIDS. Subsequent events have revealed that neither least developed countries nor the United States predicted the terms that would maximize their best interests.

C. COUNTRIES HAVE CAPITALIZED UPON THIS AMBIGUITY BY INVOKING COMPULSORY LICENSING FOR A WIDE VARIETY OF CONDITIONS AND FEARS OF FUTURE CHRONIC HEALTH PROBLEMS.

The absence of limits on what products and diseases may be covered by the Doha Declaration has had mixed consequences.

1. Positive Outcomes

First, larger developing countries with domestic pharmaceutical production capabilities have used the Declaration either to produce generic forms of patented ARVs or as leverage in negotiating significantly lower prices for ARVs from pharmaceutical companies, facilitating better treatment and more affordable prices for poor people infected with HIV. India has been the international leader in producing generic forms of patented medications and has

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82 See KATHLEEN S. SWENDIMAN, CONGRESSIONAL RESEARCH SERVICE REPORT FOR CONGRESS, MANDATORY VACCINATIONS: PRECEDENT AND CURRENT LAWS 2009 (detailing a history of the United States’ use of vaccinations to control disease outbreaks).

83 During the Swine Flu outbreak of 1976, the United States government ordered the vaccination of hundreds of thousands of U.S. citizens in an effort to create “herd immunity” to this highly contagious disease before it became uncontainable. Justin Lessler et al., Transmissibility of Swine Flu at Fort Dix, 1976, 4 J. R. Soc. Interface 755, 759-60 (2007).

84 Abbott & Reichman, supra note 69, at 937.

85 See id., at 938-39 (discussing why developing countries are hesitant to utilize the system and the United States’ reaction to the Anthrax scare in 2001).

86 For a list of countries that have produced ARVs under compulsory licenses, see LOVE, supra note 14.
created a thriving industry of exporting these medications to countries that invoke compulsory licensing under the Doha Declaration.\textsuperscript{87} India, though technically a “developing country,” has made enormous, unprecedented strides in pharmaceutical innovation and production.\textsuperscript{88} India now produces generic forms of hundreds of patented pharmaceuticals, innovations that have provided the people of India with lifesaving medications at substantially reduced costs, established a sustainable, profitable industry and enabled some countries around the world to import these medications at reduced cost under the terms of the Doha Declaration.\textsuperscript{89}

Brazil is one such case. Brazil has led the world in ensuring that its citizens have access to medications by establishing public access to AIDS treatment.\textsuperscript{90} Brazil has traditionally used its public manufacturing facilities to produce older forms of ARVs no longer covered by patent.\textsuperscript{91} However, several important ARVs, developed as “second-line treatment” to overcome resistance to the original ARVs, were subsequently patented in Brazil by foreign drug companies and could not be produced locally without offending TRIPS prior to the Doha Declaration.\textsuperscript{92} The original cost of the patented form of these medications was beyond the reach of Brazil’s public health budget.\textsuperscript{93} Until 2007, Brazil was able to use the threat of compulsory licensing under the Doha Declaration to pressure foreign drug companies to significantly lower the prices of these second-line ARVs to an amount Brazil could afford.\textsuperscript{94} In April 2007, Brazil authorized a compulsory license for Efavirenz, an ARV produced by Merck.\textsuperscript{95} Although Brazil had negotiated a reduced price for Efavirenz, from $580 to $400 per year per patient, Brazil was able to import a generic version of Efavirenz from India for only $165 per year, saving the country an estimated $30 million in public health expenditures.\textsuperscript{96}

\textsuperscript{87} India’s history of pharmaceutical production precedes TRIPS, as India has, for many years, sought to make access to medications widespread and affordable. The first planning commission established for this purpose was set up in 1950. \textit{PLANNING COMM’N FIRST FIVE YEAR PLAN}, intro., \textit{available at} http://planningcommission.nic.in/plans/planrel/fiveyr/1st/1pintro.htm. \textsuperscript{88} Id. \textsuperscript{89} Abbott & Reichman, \textit{supra} note 69, at 949. \textsuperscript{90} Id. at 951. \textsuperscript{91} Id. \textsuperscript{92} Id. \textsuperscript{93} Id. \textsuperscript{94} Id. \textsuperscript{95} Id. \textsuperscript{96} Jon Cohen, \textit{Brazil, Thailand Override Big Pharma Patents}, \textit{SCI. MAG.}, May 11, 2007, at 816; Braz. Ministry of Health Press Office, Efavirenz: Questions About Compulsory Licensing (Apr. 25, 2007), http://www.aids.gov.br/data/Pages/LUMISE77B47C8ITEMID74BBB449C36442B9B92D6ACC1D9DFC21ENIE.htm.
The ability of countries such as Brazil and India to produce generic ARVs to ensure their citizens have access to these medications has been a positive outcome of the Doha Declaration. Although countries such as Brazil, India, and Thailand are often labeled “developing countries,” in TRIPS negotiations, their perspective represents a distinct class of developing countries that is bridging the gap under TRIPS, largely by way of their domestic pharmaceutical production abilities.

2. Some Negative Consequences

Another use of threats of compulsory licensing illustrates the inconsistencies in countries’ interpretations of when they may issue compulsory licenses. The United States used compulsory licensing as leverage against pharmaceutical companies as soon as it felt threatened by the possibility of a public health emergency. In 2001, following the September 11th terrorist attacks, a small number of citizens were infected with Anthrax, and three people died as a result. In response, the United States threatened to issue compulsory licenses to produce and stockpile Ciproflaxin, an antibiotic patented by the German pharmaceutical company Bayer, forcing the company to sell the drug to the United States and Canada at heavily discounted prices. Some commenters have noted that the North American response may have been “legitimate in the circumstances.” The United States felt exceptionally vulnerable following September 11th and believed that this action was a necessary response to the threat of a full-blown bioterrorist attack. Regardless, this move reflects the blatant hypocrisy of the United States and the unequal consequences of unlimited compulsory licensing provisions in light of prior actions by the United States government.

In 1997, four years prior to the Anthrax scare in the United States, the South African government passed the South African Medicines and Related Substances Control Amendment Act of

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99 See Bradsher, supra note 15, at B7 (noting that Bayer would charge the government approximately what a generic producer of the drug would have charged the government).

100 E.g., Joseph, supra note 1, at 447

101 Id. at 446.
This law “introduce[d] a legal framework to increase the availability of affordable medicines in South Africa” through “generic substitution of off-patent medicines, transparent pricing for all medicines, and the parallel importation of patented medicines.”

The South African government specifically hoped to begin production of generic forms of patented ARVs to treat the millions of its citizens infected with HIV at that time. Forty pharmaceutical companies, with the support of the United States, sued the South African government, claiming the Act violated TRIPS. The drug companies eventually dropped the suit but it was a public relations disaster for the United States government and the WTO, prompting massive protests and outrage against the WTO.

The actions of the United States reflect how countries have used compulsory licenses to maximize their own best interests while ignoring or actively rebuking another country’s attempts to do the same. The Anthrax scare was a situation not on par with the HIV/AIDS crisis in Sub-Saharan Africa. Nonetheless, the Doha Declaration, by giving countries the ability to negotiate their own circumstances and own terms of compulsory licensing, has given countries an escape door from TRIPS whenever they feel it is in their best interest irrespective of the gravity of their healthcare needs.

Allowing countries to issue compulsory licenses for health situations notably less dire than those in other parts of the world due to their economic and political muscle decreases credibility for the policy overall. Furthermore, this unchecked flexibility garners resistance and suspicion from the pharmaceutical companies who hold patents on many lifesaving medications, erecting a barrier between least developed countries and the medications they need to combat the most serious health crises. The United States’ loud criticism of South Africa’s steps towards producing generic ARVs, and its later threats of

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102 Medicines and Related Substances Control Amendment Act, No. 90 (1997) (S. Afr.).
104 Id.
105 See NAT’L BD. OF TRADE, THE WTO DECISION ON COMPULSORY LICENSING 21 n.29 (2008), available at http://www.kommers.se/upload/Analysarkiv/Arbetsomr%C3%A5den/WTO/Handel%20och%20skydd%20i%C3%B6r%20immateriella%20r%C3%A4ttigheter%20-%20TRIPS/Rapport%20The_WTO_decision_on _compulsory/licensing.pdf (noting that South Africa introduced this law at a time when it was the country with the largest population of individuals living with HIV/AIDS).
107 NAT’L BD. OF TRADE, supra note 105, at 21 n.29.
108 Joseph, supra note 1, at 447.
compulsory licensing over Cipro, negatively affected the reputation of compulsory licensing programs.\footnote{\textit{Nat’l Bd. of Trade, supra} note 105, at 21.} This dispute pitted pharmaceutical companies against countries seeking to issue such licenses, a negative consequence that has a rippling effect on least developed countries.\footnote{\textit{Id.} at 21 n.29.}

Developing countries with domestic pharmaceutical production abilities have issued compulsory licenses for medications that do not treat life-threatening illnesses, which may go beyond the scope of the TRIPS compulsory licensing allowances and the Doha amendments, although the terms of the Doha Declaration technically allow such actions.\footnote{\textit{See, e.g., Robert Bird & Daniel R. Cahoy, The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach, 45 Am. Bus. L.J. 283, 306-07 (2008) (discussing Egypt’s issuance of a compulsory license for the erectile dysfunction drug Viagra).} See \textit{id.} at 308-09 (explaining how Egypt’s compulsory licensing scheme can undermine the strength of the Egyptian pharmaceutical industry, which supplies pharmaceuticals throughout the Middle East and North Africa).} These compulsory licenses have had negative economic and public health consequences for both these countries and their lesser developed neighbors.\footnote{\textit{Id.} at 291.} The act of compulsory licensing is “retrospective in nature” and necessarily only applies to intellectual property that already exists.\footnote{\textit{Id.}} Some have posited that pharmaceuticals that have been created with an eye on the reward granted for full patent protection would have never been developed in the face of compulsory licensing.\footnote{\textit{Id.}} From an economic standpoint, “a compulsory license is predicated on the assumption that beneficial health effects from the limitation will be significant, outweighing the loss of any innovation investment.”\footnote{\textit{Id.}} Thus, the public benefit achieved in improving and prolonging life should outweigh the economic loss of decreased return on innovation investments.

Although the countries that are home to the majority of companies that hold patents on pharmaceuticals typically (though not always) do not issue compulsory licenses for those drugs, least developed countries may nonetheless suffer from overuse of compulsory licensing through the fear of decreased FDI.

Viagra in Egypt is one such example. Egyptian law strongly favors compulsory licensing, allowing the Minister of Health to grant compulsory licenses when the quantity of medicine fails to meet national need, the price is outside the reach of most consumers, or simply because the high prices are politically burdensome.\footnote{\textit{Law on the Protection of Intellectual Property Rights, art. 23(2) (2002) (Egypt).}
laws governing compulsory licensing are broad, ambiguous, and generally afford the government wide discretion to issue compulsory licenses.\footnote{117} In 2002, after years of effort, Pfizer received regulatory approval to enter the Egyptian market with Viagra, a drug treating erectile dysfunction.\footnote{118} Two months after Pfizer’s entry into the Egyptian market, under pressure from local well-connected drug manufacturers, the government granted authorization to all companies to produce Viagra that applied to do so.\footnote{119} Although Pfizer was furious, Egypt noted they were legally allowed to issue compulsory licensing under these conditions given that, as a developing country, they were not required to comply with TRIPS until 2005 (the broadened terms of the Doha Declaration would equally have permitted such an action).\footnote{120} They also argued that reducing the cost of Viagra would benefit the poor.\footnote{121} Pfizer immediately halted their construction of a manufacturing facility in Egypt, and a Pfizer Middle Eastern representative remarked that allowing generic Viagra to be sold will “send a chill down foreign investor’s spines.”\footnote{122} Indeed, largely as a result of extensive compulsory licensing, FDI in Egypt decreased from $948 million in 1987\footnote{123} to $509.4 million in 2001-02.\footnote{124} Although FDI has increased since that time, these increases have been dominated by investments in petroleum.\footnote{125} Pharmaceutical companies have deliberately avoided investing in Egypt, a missed opportunity for a country that relies heavily on FDI.\footnote{126}

This scenario took place prior to the Doha Declaration, and prior to the time Egypt was required to come into compliance with TRIPS.\footnote{127} However, the terms of the Doha Declaration expanded

TRIPS to allow countries the freedom to “determine the grounds upon which such [compulsory] licenses are granted.” 128 Thus, under the expansive terms of the Doha Declaration, countries may issue compulsory licenses for pharmaceuticals at their discretion, and would permit Egypt to issue this type of compulsory license.

Thailand has also made extensive use of compulsory licensing under the allowances provided in the Doha Declaration. In November 2006, Thailand announced its intention to issue compulsory licenses for the ARV efavirenz, eliciting international praise for these steps towards improving treatment of HIV/AIDS. 129 After receiving an overwhelmingly positive international response, Thailand issued two more compulsory licenses, one for another ARV, Kaletra, and one in February 2007 for Plavix, a blood thinner that has been proven to prevent heart disease. 130

Additionally, Thailand has announced that it is considering breaking the patents of eleven other drugs, many of which do not treat life-threatening conditions. 131 Simultaneously, private investment in Thailand fell dramatically between 2005 and 2007. 132 Gross private investment growth fell from 10.6% to .5% in 2007, its lowest since 2000. 133 The primary cause of this decline was the dramatic decline of FDI, the main supporter of private investment growth, which declined by $10 billion in 2007. 134 Widespread compulsory licensing of pharmaceuticals is not the only factor affecting the decline in FDI in Thailand, 135 but it has had a strong negative impact on FDI. FDI has “transferred amazingly little tacit knowledge and technology, as only a handful of companies have set up research establishments in Thailand.” 136

The Viagra scenario in Egypt and Thailand’s broad usage of compulsory licensing generally illustrate how widespread, unchecked

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128 Doha Declaration ¶ 5(b).
130 Id.
132 Id.
133 Id.
134 Id. at 28
135 Id. at 7.
discretionary compulsory licensing may have poignant negative economic effects on the countries that issue them where they do not convey dramatic health benefits. Looking back at the formation of TRIPS, negotiations by the United States have been widely dominated by lobbying pressure from pharmaceutical companies. Given that this voice prevailed in TRIPS negotiations, we often consider lobbying by American pharmaceutical companies to be the only private voice in this discussion, and largely to blame for the strong patent rights in TRIPS. However, developing countries, such as Egypt, are subject to many of the same lobbying pressures of the United States. The decision of the Egyptian government to issue compulsory licenses for Viagra was the product of intense pressure from generic drug manufacturers. Furthermore, “the chairman of a large generic drug manufacturer was also the Chairman of the Health Committee in Egypt’s upper house of Parliament at the time the compulsory license was issued.”

The terms of the Doha Declaration do little to subdue the lobbying influence of localized interests that often exert powerful pressure over their national governments. Decision-making at the national level will represent the interests of the most powerful voices in those governments. This observation is not to say that national governments will always put the interests of private companies over citizens most needing access to lifesaving medication. Brazil, as previously discussed, has made access to lifesaving medications a top priority and has used compulsory licensing for that purpose, especially pertaining to HIV/AIDS, with limited negative effects on FDI. However, many countries, including the United States, Egypt, and others are subject to strong influences of private parties that have a stake in patent protection and compulsory licensing. The terms of the Doha Declaration as they currently stand may authorize too much leeway in giving governments a carte blanche to appropriate any patented medication under any circumstance.

Citizens of the most underdeveloped countries have suffered as a result of the discretionary allowances of the Doha Declaration. In this sense, the Doha Declaration has failed at achieving its most fundamental goal of “support[ing] WTO Members’ right to protect

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137 Bird & Cahoy, supra note 111, at 306.
138 Id. at 307.
139 Robert Bird and Daniel Cahoy have noted how “[u]nlike Egypt, Brazil’s compulsory license statute does not appear to come at a price of lost FDI.” Id. at 316. They attribute this outcome to Brazil’s skillful negotiations with the United States, and the fact that WTO issues compulsory licenses primarily for anti-AIDS drugs. Id. at 311-17.
140 Id. at 300-11.
public health and, in particular, promot[ing] access to medicines for all.” 141 As previously noted, about 80% of developing countries lack a functional pharmaceutical sector capable of producing ARVs. 142 In August 2003, the General Council of the WTO adopted a decision to implement the terms of Paragraph 6 of the Doha Declaration, providing criteria aimed at facilitating access to ARVs for least developed countries lacking pharmaceutical production facilities. 143 Under this decision, least developed countries may obtain generic drugs from other countries that have amended their patent legislation to produce generic drugs solely for export to countries most in need of them. 144 Two forms of notification are required by the Waiver Decision and Amendment. 145 First, countries, except those on the least developed countries list, must file a general notification of intent to make use of this system as an importing country. 146 Least developed countries are exempt from this requirement and are thus already eligible to use the system, but they must notify the WTO of their intent to use the Waiver Decision for the importation of specific drugs. 147

The WTO has done a great deal to encourage eligible importing countries, especially least developed countries, to use this system. Systematically and procedurally, the system should maximize and clear channels between least developed countries and exporting countries. Any least developed country without domestic production capabilities may invoke its terms, subject to some notification requirements. The burdens of such notification, procedurally, are minimal, facilitated by World Bank standard forms prepared for this purpose. 148

Although the Waiver Decision intended to increase access for least developed countries, these countries, particularly countries lacking domestic pharmaceutical production capacity, have hesitated to invoke its terms. Some countries, such as Ghana, Guinea, and Eritrea have issued compulsory licenses since 2005 but not under the terms of the Waiver Decision. 149 Ghana later expressed an interest to Canada as its supplier for the importation of generic pharmaceuticals,

141 Doha Declaration ¶ 4.
142 CORREA, supra note 64.
143 Implementation of Paragraph 6, supra note 13.
144 Id.
145 Id.
146 Id. at 2.
147 Id.
149 LOVE, supra note 14.
both for itself and for neighboring countries, though they have not followed through with this system. In 2007, Rwanda became the first and only country to date to follow through with the implementation of the Waiver Decision.

The reasons for the hesitance on the part of least developed countries to import inexpensive generic ARVs under the terms of the Waiver Decision are not clear, but commentators have speculated that political backlash and fear of economic sanctions have made the channels between least developed countries and eligible exporting countries tenuous. “[I]n requiring eligible importing countries to deposit a general notification of intent to use, opponents of the system may in fact have imposed a political barrier that limits its usefulness.” Particularly, some commentators have speculated that concern for adverse reaction from trading partners and the fear of appearing hostile to FDI has caused developing countries to delay issuing compulsory licenses or importing generic drugs under the Waiver Decision.

Developing countries’ fear of appearing hostile to FDI is a result of the dramatic decrease in FDI from pharmaceuticals in countries, such as Egypt, that have invoked compulsory licenses for medications in non-emergency situations. Of course, not all of Egypt’s decreased FDI can be attributed to Viagra. The Viagra situation was part of a general policy in Egypt of lax intellectual property protection for a wide variety of intellectual property, including copyrighted and trademarked goods that discouraged foreign companies from entering the Egyptian market. But issuing a compulsory license to this product encouraged Pfizer to retract its investment, and undoubtedly played a role in future companies’ decisions not to enter the Egyptian market.

Allowing countries to issue compulsory licensing for pharmaceuticals that treat non life-threatening conditions sends a message to other countries that compulsory licensing of pharmaceuticals will negatively affect their country’s well-being through decreased FDI. “Developing countries have more to ‘prove’ in regards to the quality of their national intellectual property rights

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150 Nat’l Bd. of Trade, supra note 105.
152 Abbott & Reichman, supra note 69, at 938.
153 Id. at 939.
154 Id. at 956.
155 Bird & Cahoy, supra note 111, at 308.
system than high income countries and [are] also more sensitive to losses of investment.”\textsuperscript{156} Given the “negative climate around compulsory licenses in general,”\textsuperscript{157} countries facing extreme poverty, limited FDI, and high infection rates of HIV/AIDS may opt not to invoke their rights under the Waiver Decision to import generic ARVs.

Providing ARVs to least developed countries with severely high rates of HIV/AIDS will likely increase FDI in those countries in the long-term. Least developed countries “attract virtually no FDI . . . due to low productivity, education, skills,” and an underdeveloped infrastructure.\textsuperscript{158} Countries that have historically struggled to build a sustainable infrastructure for economic growth now face the additional obstacle of a population in which one in five citizens is infected by HIV\textsuperscript{159} and life spans are cut by as much as ten to twenty years.\textsuperscript{160} Scholars note that “[t]o the extent that these countries can marshal effective investments in infrastructure, capital, education, and skills, their per-capita income levels will rise over time.”\textsuperscript{161} ARVs are the essential first step to building this infrastructure. Countries have not and cannot function under the HIV rates that have taken such a toll on their public welfare. Finding a way to ensure its population is healthy and economically productive will have long-lasting public health and economic benefits. “[A] compulsory license is predicated on the assumption that the beneficial health effects from the limitation will be significant, outweighing the loss of any innovation investment.”\textsuperscript{162} Unfortunately, other countries, including Egypt, Thailand, and the United States, are responsible for the “negative climate” surrounding compulsory licenses in general, causing least developed countries to hesitate before importing generic ARVs. While compulsory licensing is not a comprehensive answer to global health,\textsuperscript{163} for countries devastated by HIV, importing generic ARVs is the necessary first step to rebuilding a sustainable future.

\begin{footnotesize}
\textsuperscript{156} Nat’l Bd. of Trade, supra note 105, at 12.
\textsuperscript{157} Id.
\textsuperscript{159} UNAIDS, supra note 53, at 4.
\textsuperscript{160} See Stefan de Vylde, Socio-economic Causes and Consequences of HIV/AIDS 12 (Sida 1998); Pavon, supra note 55, at 54.
\textsuperscript{161} Maskus, supra note 158, at 125.
\textsuperscript{162} Bird & Cahoy, supra note 111, at 291.
\end{footnotesize}
Facilitating access to ARVs in least developed countries lacking domestic production capabilities will require more than streamlined administrative procedures through the Waiver Decision. The WTO needs to act to preserve the credibility of TRIPS compulsory licensing terms, so least developed countries do not fear negative political or economic consequences when they invoke its terms to provide their dying citizens with lifesaving medications.

CONCLUSION

The WTO should consider revising the Doha Declaration through clearer guidance and requirements for countries issuing compulsory licenses, with the goal of ensuring that least developed countries facing the most severe health crises benefit most from this declaration.

The flexibility and lack of clarification in the Doha Declaration as to what constitutes a public health crisis and what products may be subject to compulsory licensing have done more harm than good for the countries most in need of inexpensive lifesaving medications. Giving countries the flexibility to determine what constitutes a public health crisis and what pharmaceuticals they should have the rights to produce through compulsory licensing has diminished credibility for this policy, decreased FDI in many countries, and consequently erected barriers between least developed countries and the lifesaving medications they need.

I do not believe a pre-determined list of diseases and products available to treat them should be imposed to limit compulsory licensing. Although a number of diseases currently pose serious threats to public health, particularly HIV/AIDS, we have no way of predicting what diseases will threaten public health in the future, nor do we have the foresight to know what currently available medications or those later developed will be necessary to combat such a crisis. However, I believe the WTO should impose greater checks on decision-making for the terms that may be used for countries to issue compulsory licenses. If the WTO is truly looking to “harmonize intellectual property rights” through TRIPS, the discretionary terms of the Doha Declaration are a step away from such harmonization. Discretionary compulsory licensing has favored countries with domestic pharmaceutical production capacity and the economic and political muscle to threaten compulsory licensing to force pharmaceutical companies to drastically lower prices.\(^{164}\) In the long term, it has not truly benefited many developing countries that have

\(^{164}\) See supra notes 90-94 and accompanying text.
seen a decrease in FDI. The backlash and controversy surrounding compulsory licensing has led least developed countries to tread lightly before invoking its terms to import generic drugs.

An administrative body through the WTO with representatives from both developed and developing countries may be in a better position to determine when countries may issue compulsory licenses. Developing countries deserve a louder voice in WTO decision-making for compulsory licensing, overall. While the terms of the Doha Declaration favored the position taken by developing countries, subsequent usage of those terms has primarily benefited developing countries with pharmaceutical production capabilities such as India and Brazil, and developed countries such as the United States. Giving all member nations an equal voice in guiding WTO policy through decision-making of when compulsory licensing may occur will give least developed nations a louder voice in making decisions that ultimately affect their access to lifesaving medication. Compulsory licensing should not be so negatively perceived that countries in a public health crisis fear political backlash and economic downturn if they invoke its terms. The victims in this economic and political tug of war will be the citizens of least developed countries infected with HIV that do not have access to the most recent and most effective ARVs because their countries have delayed importing generic drugs. While access to ARVs has increased in recent years, the United Nations estimates that 58% of people infected with HIV are still not being treated with ARVs. The best way that countries will secure access to these patented medications will be through imports of generics under the Waiver Decision.

Undoubtedly, TRIPS does not represent the best interests of every member nation in the WTO. The strong influence of American pharmaceutical companies over these negotiations, and the fact that the agreement directly reflects American ideals regarding intellectual property rights reveal that TRIPS may not be wise international policy, especially with respect to developing countries. However, broad, discretionary compulsory licensing has not and will not reconcile the entire system of strong intellectual property rights with the disparate ideals regarding the balance between private property rights and public welfare.

165 JOINT REPORT, supra note 52, at 4.