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**INEQUITABLE CONDUCT: SHIFTING STANDARDS FOR PATENT APPLICANTS, PROSECUTORS, AND LITIGATORS**

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## \*386 I. Introduction

The Constitution grants Congress the power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”<sup>1</sup> In the 21st century, the United States’ competitive edge in the global economy is based heavily on its intellectual property assets. While the country’s merchandise trade position flounders, “[i]n 2005, U.S. trade in intellectual property produced a surplus of \$32.9 billion, up 12% from the \$29.3 billion surplus recorded a year earlier.”<sup>2</sup> Congress has a responsibility to exercise its constitutional authority to ensure a strong and reliable domestic patent system, a system that “will support and reward all innovators with high quality patents.”<sup>3</sup> The inequitable conduct doctrine, as applied by the Federal Circuit, and the severe consequences associated with losing a challenge instead cause uncertainty in the patent process. Congress should overhaul the system through comprehensive legislation--reforming the mechanisms for raising inequitable conduct claims, the analytical framework, and the available sanctions.

A robust patent system encourages domestic companies to invest in research and development, creating a cycle of increasing value. “Intellectual capital is recognized as the most important asset of many of the world’s largest and most powerful companies; it is the foundation for the market dominance and continuing profitability of leading corporations.”<sup>4</sup> Research-based businesses, in particular, rely heavily on their patent portfolios to spur growth.<sup>5</sup> A healthy patent system allows companies to risk investing revenue obtained from existing patents into the discovery and development of new inventions. For example, healthcare giant Johnson & Johnson invested approximately \$7.7 billion and software innovator Cisco spent approximately \$4.5 billion in 2007 on research and development.<sup>6</sup> The stability of these companies’ existing patent portfolios enables them to take such \*387 big risks.<sup>7</sup> Even for small companies and independent inventors, the prospect of obtaining exclusive rights gives them the incentive to invest in the development of their novel ideas. If, by way of successful inequitable conduct challenges, competitors can easily render valid patents unenforceable, incentives for inventors to create will diminish. No longer able to estimate with any certainty the future income stream from a particular patent, potential innovators will not be able to afford to invest in the discovery of key technological advances and medical breakthroughs. Innovation will lessen, triggering potential negative consequences for the country’s position in the global marketplace.

Even if innovators successfully defend an inequitable conduct challenge, they face ever-increasing litigation costs. According to Director Jon W. Dudas of the U.S. Patent and Trademark Office (PTO, Patent Office, or Office), a 2004 study showed litigation costs generally increased one percent from the prior year, while patent and intellectual property litigation costs went up thirty-two percent.<sup>8</sup> In addition, a 2001 economic survey conducted by the American Intellectual Property Law Association (AIPLA) showed the median cost to try a patent case with \$1 million to \$25 million at risk was almost \$1.5 million.<sup>9</sup> By 2007, that amount had increased to \$2.5 million.<sup>10</sup> As the amount at risk increases, so do the litigation costs.<sup>11</sup> Combined with the increased chance of facing litigation (which nearly doubled between 1988 and 2001),<sup>12</sup> “[s]uch expenses are not only staggering, but may well be expenses that neither company can afford.”<sup>13</sup>

Although these striking figures cover intellectual property litigation costs for all claims, inequitable conduct issues are a significant contributor. Resolution of highly subjective elements of the law leads to extraordinary litigation costs,<sup>14</sup> and the current inequitable conduct standard forces the courts to make just such \*388 determinations of an applicant’s state of mind.<sup>15</sup> Litigants are also less likely to settle subjective claims when they can take their chances in court. “Unfortunately for patentees, the assertion of inequitable conduct has resulted in an increasing number of patents being held unenforceable in recent years.”<sup>16</sup> The increase has been attributed, at least in part, to the Federal Circuit’s recent relaxation of the two prongs of the inequitable conduct analysis: materiality and intent.<sup>17</sup> “A lowered standard of inequitable conduct can result in increased unpredictability and decreased public confidence in the patent system as well as deter investment in innovation.”<sup>18</sup> Congress must address these problems through reform legislation.

With alleged infringers now pleading the inequitable conduct defense as a matter of course,<sup>19</sup> patent prosecutors and patent litigators face difficult questions. Since inequitable conduct standards are constantly changing and expanding, and an issued patent may only come under scrutiny in the distant future, how can patent prosecutors protect their clients and themselves? How can patent applicants and their attorneys make sure they comply with their duties to the PTO? On the other hand, patent holders and litigators must decide whether asserting patent rights against an infringer outweighs the financial cost of defending against an inequitable conduct challenge and the risk of losing the entire patent should the defendant uncover some evidence a court finds to be inequitable conduct. Given the risks, should inventors consider foregoing the patent system entirely and keeping the information as a trade secret, even though the public would lose out on the disclosure? With shifting inequitable conduct standards, how are patent prosecutors and patent litigators to navigate the waters? Unless Congress

enacts significant amendments to the inequitable conduct sections of the Patent Act, courts will continue to wrestle with these difficult subjective determinations and patent holders will face great uncertainty in patent procurement and litigation.

Part II of this Article discusses the historical and analytical underpinnings of the doctrine of inequitable conduct and how the standards have changed and expanded over time. Part III looks at additional complications for patent prosecutors and litigators caused by the conflict between recent Federal Circuit law and proposed regulations promulgated by the PTO. In Part IV, several proposals for comprehensive reform are presented and evaluated.

## **\*389 II. View of the Landscape--The Doctrine of Inequitable Conduct**

### **A. The Doctrine of Inequitable Conduct Has Judicial and Administrative Origins**

The nation's early patent statutes made no mention of the doctrine of inequitable conduct. Rather, the Supreme Court developed the premise based on the equitable considerations of "unclean hands," a doctrine precluding a party which engaged in wrongful conduct that relates in some significant way to the claim asserted from obtaining relief.<sup>20</sup> The Court first applied the unclean hands doctrine to patent infringement in *Keystone Driller Co. v. General Excavator Co.*<sup>21</sup> Because of the plaintiff's "highly reprehensible conduct" in suppressing prior art related to the patents-in-suit, the circuit court dismissed the plaintiff's infringement actions.<sup>22</sup> The Supreme Court upheld the ruling, effectively rendering the plaintiff's patents unenforceable.<sup>23</sup> In the 1945 *Precision Manufacturing* case, the Supreme Court explicitly recognized inequitable conduct by a patent applicant as grounds for unenforceability.<sup>24</sup> There, the Court emphasized, the far-reaching social and economic consequences of a patent "give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct."<sup>25</sup>

Inequitable conduct is measured in part by reference to the duties owed to the PTO.<sup>26</sup> "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability . . . ."<sup>27</sup> "The rationale for the high level of candor and disclosure in patent cases is that every right granted to a patentee is conferred by the Patent Office, which must protect the public from fraudulently obtained patent \*390 monopolies."<sup>28</sup> Further, "no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct."<sup>29</sup> The applicant's duty to the PTO is enforced through the claim of inequitable conduct.

Although inequitable conduct is frequently referred to as "fraud on the Patent Office," its reach goes beyond acts considered common law fraud.<sup>30</sup> Inequitable conduct includes an "affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive."<sup>31</sup> These two threshold requirements--materiality and intent to deceive--are questions of fact, which must be proven by clear and convincing evidence.<sup>32</sup> If a patent challenger satisfies the two threshold requirements of the test, the court then determines "whether the applicant's conduct is so culpable, based on a balancing of the materiality and intent under the circumstances, that the patent should be rendered unenforceable."<sup>33</sup> Such careful balancing requires the exercise of judicial discretion.<sup>34</sup> Thus, "unlike questions of invalidity, inequitable conduct is decided by a judge, not a jury."<sup>35</sup>

The potential consequences of failing to beat an inequitable conduct challenge are severe and far-reaching. With respect to the patent at issue, the patent holder loses the ability to enforce his rights not just for the relevant claim or claims, but for the entire patent, and not just against the particular defendant, but against any potential infringer.<sup>36</sup> Related patents, originally part of the suit but no longer asserted, may also be rendered unenforceable.<sup>37</sup> The patent holder may further lose any royalties previously paid on the knocked-out patent.<sup>38</sup> In "exceptional cases," unsuccessful plaintiffs may be forced to pay attorneys' fees to the prevailing \*391 party.<sup>39</sup> Patentees also stand to be held liable for damages under antitrust, trade, or securities laws.<sup>40</sup> For example, *Purdue Pharma L.P.*'s loss of its patents spawned approximately sixty antitrust suits<sup>41</sup> alleging *Purdue* had fraudulently obtained its patents to "thwart generic competition for *OxyContin*®."<sup>42</sup> Importantly, because the applicant's attorney usually makes decisions about the scope of disclosure to the PTO, applicants risk waiving attorney-client and work-product privileges.<sup>43</sup> Even the prosecuting patent agent or attorney is exposed to possible professional discipline, as the Patent Office has the authority to "suspend or exclude . . . from further practice before the Patent and Trademark Office, any person, agent or attorney shown to be . . . guilty of gross misconduct."<sup>44</sup> Finally, regardless of whether the inequitable conduct challenge is overcome, the allegation of dishonesty can harm the parties' and their attorneys' reputations.<sup>45</sup>

## **B. Policy Considerations Support Having Some Form of Inequitable Conduct Doctrine**

A strong patent system encourages continued innovation not only by protecting valid patents, but by ensuring only high quality, valid patents issue in the first place. Improperly issued patents may stifle innovation by taking knowledge out of the public domain, by allowing parties to demand license fees for the use of that public knowledge, and by forcing potential innovators out of an area of research.<sup>46</sup> Moreover, an issued patent is presumed valid,<sup>47</sup> making it more difficult for competitors to challenge the holder's property rights.

**\*392** A robust examination process based on open, collaborative communication between applicant and examiner will ensure only valid patents issue. Under the U.S. system, "the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability."<sup>48</sup> Because our domestic process currently functions *ex parte*, without a formal opposition system through which patent challengers may submit relevant prior art before a patent issues, examination is done solely on the basis of information discovered by the examiner and supplied by the applicant.<sup>49</sup> With the PTO struggling to allocate resources to an ever-increasing backlog of unexamined patent applications, these days the Office is relying even more on the applicant's honest and forthcoming aid to expedite application review.<sup>50</sup> Patent examiners are well-versed in their particular area of technology<sup>51</sup> and are fully capable of reviewing the literature, but applicants, being immersed in research on the specific topic of the application, are in the best position to know the scope of relevant art. The purpose of the inequitable conduct doctrine is clear--to encourage applicants to "work with examiners to secure the issuance of a completely valid patent."<sup>52</sup> However, given the recent trends, discussed *infra* in Part III, the changing inequitable conduct landscape makes communication with the Patent Office a risky business and thus, hinders the collaborative examination process.

## **III. Uneven Ground--Recent Expansion of the Federal Circuit Standards for Inequitable Conduct and the Conflict with PTO Regulations**

The rise of inequitable conduct allegations in the 1980s led the Federal Circuit to criticize the defense as "overplayed" and "cluttering up the patent system,"<sup>53</sup> and to lament, "[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague."<sup>54</sup> The Federal Circuit's **\*393** decision in *Kingsdown Medical Consultants*<sup>55</sup> and the PTO's 1992 amendment to the Rule 56 duty of disclosure were largely considered to have curbed flagrant charges of inequitable conduct.<sup>56</sup> However, in the twenty years since *Kingsdown*, the Federal Circuit has changed and relaxed the inequitable conduct standards, leaving a confusing quagmire for patent applicants, prosecutors, and litigants to navigate.

### **A. The Federal Circuit Uses Five Different Tests for Materiality**

Codified in 1977, PTO Rule 56 defined materiality as information "a reasonable examiner would consider [] important in deciding whether to allow the application to issue as a patent."<sup>57</sup> In 1992, the PTO replaced the "broad[] and all-encompassing"<sup>58</sup> reasonable examiner standard with a more limited one, stating:

[I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position taken by the applicant in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.<sup>59</sup> The revised standard was intended to "address criticism concerning a perceived lack of certainty in the materiality standard, . . . [to] minimize the burden of litigation on the question of inequitable conduct before the [Patent] Office, . . . [and] to present a clearer and more objective definition of what information the Office considers material to patentability."<sup>60</sup>

Despite the PTO's adoption of this single, objective standard for materiality, subsequent Federal Circuit opinions referred to as many as five different tests, recently going so far as to state there is "no reason [] to be bound by any single \*394 standard."<sup>61</sup> In *Digital Control*, the Federal Circuit applied the pre-1992 "reasonable examiner" standard even though the conduct at issue occurred in connection with applications filed after 1992.<sup>62</sup> Although the appellate court acknowledged the new rule created "an arguably narrow[] standard [for] materiality,"<sup>63</sup> it held the PTO's rule change was not intended to "supplant or replace" the broader standard, but instead "merely provide[d] an additional test of materiality."<sup>64</sup> A recent Federal Circuit opinion described the "reasonable examiner" standard even more broadly, as a very low hurdle to overcome, in which information is material if it "might have been important" to the Examiner's decision.<sup>65</sup> Essentially, the Federal Circuit refused to let the PTO overrule its case law precedent despite the fact the court relied on the pre-1992 PTO rule to develop its judicial standards.

Along with the two PTO Rule 56 standards, the Federal Circuit uses three other tests for materiality, developed by the court before the 1977 advent of Rule 56: 1) the objective "but for" test "where the misrepresentation was so material the patent should not have issued;" 2) the subjective "but for" test "where the misrepresentation actually caused the examiner to approve the patent application when he would not otherwise have done so;" and 3) the "but it may have" test "where the misrepresentation may have influenced the [patent] examiner in the course of prosecution."<sup>66</sup> Consistent with its position that the revised Rule 56 standard merely added to the analytical mix, the Federal Circuit has confirmed even these three pre-1977 tests are still in play.<sup>67</sup> Thus, represented among the five standards are objective and subjective measures. In addition, different levels of significance are placed on omitted information (important, influential, or crucial to an examiner's decision).

The Federal Circuit described the pre-1992 "reasonable examiner" standard as the broadest, encompassing the other four.<sup>68</sup> Because only a threshold showing of materiality is needed before a court can proceed to analysis of the intent prong, many courts initially apply this lowest-level standard.<sup>69</sup> Whether or not conduct meets one of the other four standards is a factor in the court's balancing between \*395 materiality and intent.<sup>70</sup> "[T]o the extent that one standard requires a higher showing of materiality than another standard," courts may require a lesser showing of intent.<sup>71</sup> For example, where "a reasonable examiner would merely have considered particular information to be important but not crucial to his decision," courts may require a stronger showing of facts from which intent may be inferred.<sup>72</sup> "Conversely, where an objective 'but for' standard of materiality is shown, 'a lesser showing [of intent] may be sufficient.'"<sup>73</sup>

Under these confusing and overlapping standards, courts have found a wide range of acts, statements, and omissions to satisfy the materiality requirement. Certain types of culpable conduct involve the content of the application, such as filing unduly broad claims unsupported by the specification<sup>74</sup> or failing to disclose the best mode of practicing the invention.<sup>75</sup> In *Novo Nordisk*, although a key experiment had not actually been performed, the patentee drafted its description using past tense language rather than present tense required for prophetic examples.<sup>76</sup> Since the examiner relied on the completed experiment in assessing enablement of the claims, the court found the misrepresentation was material.<sup>77</sup> Similarly, the *Purdue Pharma* court found materiality for the patentee's repeated assertions that a "result" was "surprisingly discovered" when based only on an inventor's "insight" rather than experimental data, because the assertions were made to distinguish the claimed invention from prior art.<sup>78</sup>

Lowering the materiality standard has expanded what kinds of information and prior art qualify. The *McKesson* court held office actions and notices of allowance in substantially related, co-pending cases were material and found inequitable conduct despite the prosecutor's disclosure of the co-pending applications to the examiner.<sup>79</sup> Declarations submitted by applicants in response to PTO requests are subject to even greater scrutiny because they are "inherently material" and because of "the inability of the examiner to investigate the facts."<sup>80</sup> \*396 Patent holders have been cited for failing to disclose a declarant's relationship with the applicant, even though the declaration contained only literally true statements, on the ground the information was relevant to the examiner's evaluation of the declarant's bias.<sup>81</sup> Material information has been deemed to include prior art from unexpected sources, such as a scientist's notes from a poster presentation for which the applicant did cite the abstract.<sup>82</sup> Even information unrelated to the claimed subject matter could be relevant, because a prior art publication may be material "even if disclosure of that misstatement or omission would not have rendered the invention unpatentable."<sup>83</sup> Applicants cannot err on the side of caution either, as "'burying' a material reference in a stack of irrelevant information" can also give rise to liability.<sup>84</sup>

Under the Federal Circuit standards, even acts or omissions having no bearing on the content or validity of a patent application have been classified as material.<sup>85</sup> In *General Electro Music Corp.*, the Federal Circuit affirmed an inequitable conduct ruling where the applicant's attorney submitted a declaration in which he falsely stated he had conducted a "careful

and thorough” search of the prior art.<sup>86</sup> While an examiner would reasonably rely on such a statement in performing his examination, other seemingly less egregious conduct has fallen short as well. For example, materiality has been found for failing to disclose a settlement agreement,<sup>87</sup> neglecting to disclose a working relationship between inventors and collaborating scientists,<sup>88</sup> and even for improperly claiming eligibility for small entity status for maintenance fee payments.<sup>89</sup>

Having multiple materiality standards presents difficulties for patent applicants and district courts. Applicants are left to guess what information should be disclosed. The purpose of the duty of disclosure is to assist the Patent Office in performing effective examinations, and the Patent Office has told applicants, \*397 “information is not material unless it comes within the definition of 37 C.F.R. 1.56(b)(1) or (2). If information is not material, there is no duty to disclose the information to the Patent Office.”<sup>90</sup> Yet the Federal Circuit has imposed a responsibility on applicants that goes far beyond what the PTO requires. Fearful of losing their patents for failure to cite an allegedly material piece of information, applicants often take one of two tacks: they either “(i) ‘dump’ everything they have on the PTO (sometimes many boxes of printed documents), or (ii) do not search the prior art, and thus in turn have little or nothing to give the PTO.”<sup>91</sup> Given that effective examination requires fruitful disclosure by applicants, and not just disclosure, neither of these two approaches is “helpful to the patent examiner or the patent system in general.”<sup>92</sup> The various subjective standards and the Federal Circuit’s inconsistent review of trial court decisions fail to provide district courts with the guidance they need to make reasoned decisions.

## **B. Judicial Analysis of Intent to Deceive Is Highly Subjective**

Since intent to mislead the Patent Office is a subjective determination “directed at the state of mind of the patent applicant or the applicant’s attorney,”<sup>93</sup> direct evidence of such intent is rarely available. Therefore, in the absence of a credible explanation, intent may be inferred from circumstantial evidence, including the “facts and circumstances surrounding the applicant’s conduct.”<sup>94</sup>

After denouncing the proliferation of the inequitable conduct defense as “an absolute plague” in 1988, the Federal Circuit acted to limit a district court’s discretion in finding intent to deceive in *Kingsdown*.<sup>95</sup> Prior to this ruling, Federal Circuit precedent held a showing of “gross negligence” was sufficient to prove intent to deceive.<sup>96</sup> The *Kingsdown* court reversed that premise, holding instead that “a finding that particular conduct amounts to ‘gross negligence’ does not of itself justify an inference of 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.”<sup>97</sup> After *Kingsdown*, then, “intent to deceive could be inferred from the facts and circumstances \*398 surrounding a knowing failure to disclose material information.”<sup>98</sup> This change, along with the PTO’s revision of Rule 56, made inequitable conduct much more difficult to prove.

Under the traditional Braun standard, an accused infringer cannot rely solely on undisclosed prior art’s materiality to prove the intent element.<sup>99</sup> Once materiality and intent are proven by clear and convincing evidence, “[t]he court must then determine whether the questioned conduct amounts to inequitable conduct by balancing the levels of materiality and intent, ‘with a greater showing of one factor allowing a lesser showing of the other.’”<sup>100</sup>

Recent Federal Circuit opinions have confused the Braun balancing test, instead allowing the inference of intent from a high level of materiality without any direct or circumstantial showing of knowing intent to deceive. “In other words, a high level of one [element] might offset a low level of the other so that in some cases inequitable conduct is found despite very little evidence of deliberate misconduct.”<sup>101</sup> The latest opinions have essentially collapsed the two inquiries into a single test for materiality.<sup>102</sup>

At the same time, the Federal Circuit has abandoned *Kingsdown*’s scienter requirement. In *Novo Nordisk*, in which a prophetic example was erroneously drafted in past tense, the court found an intent to deceive despite the lack of any evidence the foreign inventor either understood the implication of using the past tense, or that he disclosed to his attorneys the example’s prophetic nature.<sup>103</sup> The court imputed knowledge of the Patent Office’s verb tense requirements from the attorney to the inventor, and determined the inventor therefore “knew or should have known” of the materiality of the information.<sup>104</sup> From that presumed knowledge, the court then inferred a deceptive intent.<sup>105</sup> Intent to deceive was concluded without any direct knowledge of materiality whatsoever, in stark contrast to the *Kingsdown* rule.

\*399 Similarly, in *Ferring v. Barr*, the applicant failed to disclose that several non-inventor declarants on requested affidavits had either received funding from or had worked for *Ferring* previously.<sup>106</sup> The Federal Circuit held that if omitted information is “highly material” and “the applicant knew of the information,” intent to mislead can be inferred where the applicant “knew

or should have known of the materiality of the [withheld] information” and failed to provide a “credible explanation” for withholding it.<sup>107</sup> Apparently, the applicant should have known the patent examiner was requesting declarations not just from technical experts, but from completely independent ones.<sup>108</sup> Because the applicant should have known, but did not, the court inferred a deliberate intent to deceive the PTO about the source of the declarations.<sup>109</sup>

In its 2007 *McKesson v. Bridge* opinion, the court went further along this path. There, the attorney argued the omitted references were cumulative to other art on record, but the district court disagreed.<sup>110</sup> Without any notes from the prosecution file to corroborate the attorney’s testimony, the district court found his testimony unbelievable, and determined he “knew or should have known” about the materiality.<sup>111</sup> In part based on “[t]he high materiality of the withheld prior art,” the Federal Circuit concluded “the district court had not committed clear error by inferring an intent to deceive.”<sup>112</sup> The Federal Circuit has only foreclosed the inference of intent from materiality in situations where “the materiality of the undisclosed information is relatively low.”<sup>113</sup> Therefore, highly or even moderately material information may give rise to an inference of intent under the “should have known” standard.

The Federal Circuit has also rendered inconsistent opinions on the importance of a good faith explanation of the conduct at issue on the intent analysis. In 2005, the court held, “[I]n the absence of a credible explanation, intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure \*400 to disclose material information.”<sup>114</sup> The *M. Eagles Tool Warehouse* court opined in 2006 that a lack of a good faith explanation for the nondisclosure alone “cannot constitute clear and convincing evidence sufficient to support a determination of culpable intent.”<sup>115</sup> However, the tables turned in 2007 with *McKesson*, where “the lack of ‘a credible explanation for the nondisclosure’” was a key factor in the inequitable conduct ruling.<sup>116</sup> Similarly, in *Ferring*, interpreting the “generally inferred” language from *Bruno*, the court held, “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.”<sup>117</sup>

Through these decisions, the Federal Circuit has “revived a ‘should have known’ standard for assessing intent thought to have been laid to rest by the *Kingsdown* opinion.”<sup>118</sup> The intent analysis has become even more nebulous because it incorporates the relaxed standard for materiality discussed above--even innocent, unknowing omissions of tangentially related information are subject to scrutiny. Overall, patent applicants and prosecutors are left with little idea of how to comply with their duties to the PTO or how to avoid falling prey to an inequitable conduct challenge. In addition, if patent applicants are responsible for disclosing all highly or moderately material information, are they now obligated by the Federal Circuit to perform patentability searches, though the PTO expressly does not require them?<sup>119</sup> Small inventors, with little, if any, access to literature searching databases, nor the financial resources to use them, will be disproportionately burdened. With the great expense of filing and prosecuting a patent application, requiring a patentability search may be so onerous as to take small inventors out of the market altogether.

By expanding the scope of what constitutes inequitable conduct and merging the materiality and intent analyses, the Federal Circuit risks a return to the inequitable conduct “plague” of the pre-*Kingsdown* era. In a dissent offered in *Ferring*, Judge Pauline Newman argued the majority’s decision was in conflict with *Kingsdown*, which required separate, independent proof of materiality and intent.<sup>120</sup> \*401 The majority instead inferred intent from materiality, in effect relying on the same evidence to prove both elements.<sup>121</sup> Using a “should have known” standard improperly allows an inference of intent based on presumed knowledge, with no actual or even circumstantial evidence of any deceptive intent.<sup>122</sup> Similarly, in *McKesson*, Judge Newman emphasized, “In *Kingsdown*, we observed that, ‘[t]o be guilty of inequitable conduct, one must have intended to act inequitably.’”<sup>123</sup> Without that threshold requirement, she opined, “This court returns to the ‘plague’ of encouraging unwarranted charges of inequitable conduct, spawning the opportunistic litigation that here [in *McKesson*] succeeded despite consistently contrary precedent.”<sup>124</sup>

### **C. Proposed Disclosure Rules from the PTO Foreshadow Potential Inequitable Conduct Problems**

Through regulation, the Patent Office has attempted to inform the Federal Circuit of what materiality and intent standards will help it provide effective patent examination. In the past, the Office worked to moderate its requirements, as with the 1992 Rule 56 revision, in an effort to balance the benefits of full disclosure with the burdens on patent applicants.<sup>125</sup> Nevertheless, as discussed above, the Federal Circuit has taken upon itself to define the scope of inequitable conduct, moving toward stricter requirements for patentees. Complicating the landscape is the Patent Office’s recent reaction to its ever-increasing backlog of unexamined patent applications.<sup>126</sup> Trying to streamline its operations, the Patent Office has

proposed new rules governing the scope and detail of information applicants must submit.<sup>127</sup> These new rules and the conflicts they create with Federal Circuit standards will expose applicants to even greater risk of inequitable conduct challenges.

The first issue arises from the Office's proposed changes to the information disclosure requirements, under which applicants would have to provide an explanation for any submitted reference above a twenty-document threshold.<sup>128</sup> Based on a survey showing twenty or fewer references were submitted for 85% of \*402 applications, the Office determined "a threshold of twenty documents best balances the interests of the Office and of the applicants."<sup>129</sup> Although the Office is trying to minimize the impact of this new rule by setting a threshold number of references,<sup>130</sup> for affected applicants, the increased burden and risks will be substantial. "The required explanation must identify information in each document that is relevant to the claimed invention or supporting specification."<sup>131</sup> Of course, after McKesson, contrary office actions and notices of allowance in substantially related, co-pending cases are relevant.<sup>132</sup> Once an applicant submits these individual documents, the twenty-reference threshold could be reached rather quickly in many more than 15% of cases.<sup>133</sup> The Federal Trade Commission solicited feedback on these proposals and discovered potential patentees are justifiably concerned about the time and cost associated with "requiring attorneys to understand and properly describe all references."<sup>134</sup> Applicants are concerned "even slight errors in description could fuel claims of mischaracterization and inequitable conduct."<sup>135</sup> This apprehension is especially well-founded in light of the recent expansion in the Federal Circuit's inequitable conduct jurisprudence. On one hand, the Federal Circuit has lowered the bar as to what information is material, and intent to deceive may be inferred even where the applicant and attorney were unaware of the information or its materiality. On the other hand, the PTO and congressional proposals force applicants to choose between limiting their disclosures and disclosing more but triggering the detailed review and relevance statement obligations.

The second complication stems from patentability search requirements. Until now, the PTO has imposed no affirmative duty on applicants to perform a patentability search.<sup>136</sup> However, the Office has now followed the Federal Circuit's lead by proposing just such a search requirement.<sup>137</sup> Under the proposed rules for claim examination, "when an applicant presents more than five independent claims \*403 or more than twenty-five total claims in an application," he is required to submit an "examination support document," including a "statement that a preexamination search . . . was conducted."<sup>138</sup> On April 1, 2008, a federal district court granted summary judgment against the Patent Office, holding the proposed rules were substantive and therefore exceeded the scope of the PTO's rulemaking authority.<sup>139</sup> However, in March 2009, the PTO won a partially successful appeal before the Federal Circuit and will likely continue to pursue various mechanisms to ease its workload.<sup>140</sup>

In its March 2009 decision in *Tafas v. Doll*, the Federal Circuit reversed the district court's summary judgment ruling, holding the PTO's proposed claim examination rules are procedural rather than substantive and thus fall within the scope of the PTO's rulemaking authority.<sup>141</sup> In light of this result, search requirements may become a reality. Congress included a search requirement in the Patent Reform Act of 2007 with the PTO's full support.<sup>142</sup> The proposed amendment to 35 U.S.C. § 123 states, "The Director shall, by regulation, require that an applicant for a patent under this title submit to the Director--(1) a search report and analysis relevant to patentability; and (2) any other information relevant to patentability that the Director, in his discretion, determines necessary."<sup>143</sup> The Patent Reform Act of 2008 addresses the issue with somewhat more nebulous language, allowing the PTO to "offer incentives to applicants who submit a search report, a patentability analysis, or other information relevant to patentability," including prosecution flexibility, modifications to requirements for obtaining patent term adjustments, or modifications to imposed fees.<sup>144</sup>

A new search and analysis requirement would cause several significant problems for applicants. First, the language in the proposed rule and statute provide almost no guidance on what constitutes an acceptable search. Also, a search requirement will significantly increase the costs of procuring patents, as professional searchers may charge anywhere from several hundred dollars for a simple mechanical invention to a thousand dollars or more for complex chemical inventions.<sup>145</sup> The search proposal will create yet another liability risk, as "the search and patentability analysis would be available for [an] infringer to dissect and \*404 assert that, as to the scope of the search or for isolated passages, the patent applicant failed its responsibility to fully identify and/or disclose the content of the prior art or properly explain its relevance."<sup>146</sup>

Both of these proposals present additional litigation risks. If patent attorneys must document and explain, on the record, every decision they make about the relevance of certain art or other information, any claim amendment will be evaluated through that lens--patent holders may have to sacrifice claim scope under the doctrine of equivalents because of prosecution history estoppel.<sup>147</sup> Such disclosures also may constitute a waiver of attorney-client privilege and attorney work product protection.<sup>148</sup>



## **D. Changing and Conflicting Inequitable Conduct Standards Destabilize the Patent Process**

The Federal Circuit's relaxed standards for inequitable conduct fail to further the policy rationales that originally supported the doctrine's creation, and thus, the stability of the patent system has been undermined. Patentees and prosecutors face changing rules, making it difficult to figure out how to comply with the duties imposed by the PTO and the additional burdens set by judicial decree. The evolution seems to be driven by the courts rather than Congress. In the absence of congressional input to clarify the principles, patentees must guess what formula applies now and what might apply when the patent is litigated perhaps a decade or more in the future. As Judge Newman emphasized in *McKesson*, the relaxed standards and unclear tests encourage frivolous charges of inequitable conduct.<sup>149</sup> Alleged infringers have a much better chance of knocking out a patent than in years past, making even valid patents a much more precarious property holding. With this trend, competitors will be more likely to infringe patents, knowing patent holders will be forced to weigh the benefits of asserting the patent against the expense of litigation and risk of losing the patent altogether. If valid patents are not scrupulously upheld, the incentives to invent will dissipate, and innovation will slow dramatically.

### **\*405 IV. Clearing the Path--Improving the Inequitable Conduct Doctrine**

#### **A. Congress Should Overrule the Federal Circuit by Passing Comprehensive Inequitable Conduct Reform**

To settle the law of inequitable conduct and provide definitive guidance in this area, Congress should overrule recent Federal Circuit precedent and the PTO's proposed rules by amending the Patent Act. To ensure valid patents are upheld, such legislation should: (1) require inequitable conduct be pled with particularity, (2) clearly define the materiality and intent standards, (3) require a showing that the misconduct caused patent issuance before sanctions are imposed, and (4) give courts discretion in fashioning suitable remedies. The proposed Senate Bill S.1145 (Patent Reform Act of 2007) is a good starting point, but on some issues, more sweeping changes should be implemented. As the proposed Patent Reform Act of 2008 lacks any mention of changes in the inequitable conduct arena, the following discussion refers to the bills considered by the Senate and House during the 2007-2008 session.

##### **1. Inequitable Conduct Pled with Particularity**

To avoid frivolous claims of inequitable conduct, patent reform should require the affirmative defense be pled with particularity. The proposed Senate bill addresses this issue, stating, "[i]n actions involving allegations of inequitable conduct before the Office, the party asserting the defense or claim shall comply with the pleading requirements set forth under Federal Rules of Civil Procedure 9(b)."<sup>150</sup> The change puts inequitable conduct on similar ground as traditional fraud claims.<sup>151</sup> Courts have typically held the particularity rule requires one to support a claim with specific facts "giving rise to a strong inference" of scienter or fraudulent intent such that "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged."<sup>152</sup>

The Senate Subcommittee on Intellectual Property felt this change would address "some concerns that inequitable conduct is 'over plead[ed]' and a tool of harassment."<sup>153</sup> But the proposed particularity policy does not go far enough to protect valid patents from unwarranted attack. To truly limit frivolous claims, legislation should impose an additional "pleading limitation requiring that at least \*406 one asserted claim first be held invalid."<sup>154</sup> "In other words, the defense would not be available to a defendant until it has already won the case."<sup>155</sup> Logistically, because inequitable conduct is always pled along with invalidity, the amended statute should either provide a mechanism for bifurcation of the counterclaims or refer to Federal Rule of Civil Procedure 42(b).<sup>156</sup> The new requirement would make it more difficult for patent challengers to assert the defense, as they would have to invest resources to uncover specific information needed to make the allegation. However, most relevant information, including an application's prosecution history or relevant prior art, is publicly available. A heightened particularity requirement might allow some instances of misconduct to go undetected, but because there is little evidence of widespread fraud on the Patent Office,<sup>157</sup> the change is worth it to discourage frivolous claims against legitimate patent holders.

##### **2. Clear, Defined Test for Inequitable Conduct**

Both the House and Senate reform proposals reinforce that challengers must prove the materiality and intent elements of inequitable conduct by clear and convincing evidence.<sup>158</sup> However, any new law must also clearly define the standards for materiality and intent and the relationship between them.

For the materiality prong, Congress should overrule the Federal Circuit by dictating one single standard rather than the five currently in play. The Senate proposal mirrors the current Rule 56 language, which is appropriate because the Patent Office should have a say in defining what information it needs to perform accurate examinations. Thus, new statutory language should read, “Information shall be considered material for purposes of subsection (a) if (1) a reasonable patent examiner would consider such information important in deciding whether to allow the patent application; and (2) such information is not cumulative to information already of record in the application.”<sup>159</sup> As noted by the Senate Judiciary Committee, “[C]ertain court decisions appear to emphasize improperly the first part \*407 of this definition (reasonably important to an examiner) without giving necessary consideration to the latter part of the definition (in deciding whether to allow the patent).”<sup>160</sup> By codifying the definition, Congress would emphasize the entire definition must be satisfied.

Furthermore, statutory text for the intent prong should implement the Federal Circuit’s 1988 *Kingsdown* scienter requirement. The Senate proposal moves in this direction, stating, “Intent to deceive the Office may be inferred . . . , but the inference may not be based solely on the gross negligence of the patent owner or its representative, or on the materiality of the information misrepresented or not disclosed.”<sup>161</sup> However, in addition to defining what does not support an inference, the House bill and patent reform groups define what information does. An inference of intent should be allowed only on the basis of “specific facts beyond” the materiality of the information misrepresented or omitted which “indicate conscious or deliberate behavior on the part of the patentee, its agents, or another person with a duty of disclosure to the Office, to not disclose material information or to submit materially false information”<sup>162</sup> when “viewed in light of all the evidence, including evidence indicative of good faith.”<sup>163</sup> Examples might include failing to disclose a prior art reference in a continuation application that was provided for the parent application, failing to submit negative experimental data in the inventor’s possession, or making arguments to the Office that clearly contradict information known to the applicant.

Clear, manageable standards for inequitable conduct will put patent applicants and prosecutors on notice as to exactly how to comply with their duty of disclosure and duty of candor and good faith toward the Patent Office, and will discourage patent challengers from launching frivolous claims against valid patents. Implementing such changes would not create new, more rigorous standards, but would simply overrule the expansion created by recent Federal Circuit decisions and mark a return to the stricter standards from the late 1980s and early 1990s.

### 3. Causation Requirement

Successful inequitable conduct reform starts with limiting an alleged infringer’s power to render a valid patent unenforceable. Several commentators have suggested an additional evidentiary hurdle that would protect valid patents even in cases where deceptive intent is found, where a patent challenger would \*408 have to “show that but for the inequitable conduct the patent would not have been allowed.”<sup>164</sup> The Coalition for 21st Century Patent Reform (hereinafter, Coalition), a diversified group of over 40 global corporations, proposes that where intent to deceive is found, “[a] sanction may be imposed based upon misconduct . . . only if . . . acting reasonably in the absence of such deception and on the record before it, the Office would not have allowed one or more of the claims.”<sup>165</sup>

Of course, the inequitable conduct doctrine is intended to curb fraudulent behavior before the Patent Office, regardless of whether a valid patent results. With the proposed causation element, how would the Patent Office deter misconduct in cases where valid patents issue? The proposed change does reduce the deterrent effect of patent unenforceability, but the system is still protected. First, in the current litigious environment, patent holders have no guarantee their valid patents will hold up in court. Second, an applicant who believes he is entitled to a patent has no incentive to intentionally mislead the Patent Office. Third, with the proposed opposition rules, the entire process will be subject to greater oversight by third parties. Finally, patent attorneys and agents are subject to professional discipline by the PTO and under rules of professional responsibility if they engage in any misconduct, not just that which falls under the inequitable conduct definition. With other deterrence mechanisms in place, a causation requirement is an appropriate mechanism for discouraging capricious inequitable conduct claims.

### 4. Judicial Discretion for Defining Remedies

Under the current inequitable conduct regime, courts have little, if any, discretion to fashion a remedy proportionate to the misconduct. The only latitude courts may exercise is in balancing the findings of materiality and intent to decide whether to find inequitable conduct in the first place. Once that decision is made, the least severe remedy the court can impose is to render the entire patent at issue unenforceable. Of course, under *Nilssen v. Osram Sylvania, Inc.*,<sup>166</sup> district courts have the

authority to impose greater sanctions such as declaring related patents no longer in suit unenforceable.<sup>167</sup> However, even the deterrent effect of complete unenforceability may not warrant denying courts the chance to evaluate the circumstances of each case. Courts traditionally have flexibility to tailor remedies in equitable matters, are equipped to do so, and should be allowed to do so here.

Amendments to the patent law must therefore give courts greater freedom to develop a remedy for each particular case. The Senate proposal opens the door a \*409 bit, but requires that a “court, using its discretion, shall . . . (1) [h]old the patent unenforceable[,] (2) [h]old 1 or more claims of the patent unenforceable,” and/or (3) deny the plaintiff equitable relief and limit the plaintiff’s remedy for infringement to reasonable royalties.<sup>168</sup> The passed House bill similarly requires courts to choose a remedy from this narrow list of choices.<sup>169</sup>

Congress should adopt the more comprehensive and flexible plan suggested by the Coalition. The Coalition text specifically directs courts to “impose a sanction proportionate to redress the harm to the public interest caused by the misconduct.”<sup>170</sup> In addition, the list of remedies is not exclusive--“ [a] sanction may (a) deny equitable relief to the patent holder, (b) assess attorneys fees and costs, (c) hold one or more of the claims of the patent to which the misconduct relates unenforceable, or (d) in extraordinary situations, hold all of the claims of the patent unenforceable.”<sup>171</sup> The language emphasizes the severe nature of knocking out an entire patent and reserves that sanction for the most egregious cases. The “may” language in the proposed preamble, in contrast to Congress’s “shall” wording, highlights that courts have the equitable discretion to be creative in designing an appropriate remedy.

## **B. Alternative Proposals**

Influential legislators, scholars, and commentators have set out alternative proposals to those described above, but none are as comprehensive or specific as they need to be. As we have seen, the Federal Circuit and Patent Office standards are diverging, leaving patent applicants unsure of how to procure and protect intellectual property rights. “Congress has not enacted comprehensive patent law reform in more than 50 years,”<sup>172</sup> and given the difficulties of reaching consensus on these issues, major revisions in how inequitable conduct claims are heard and analyzed must be accomplished in a thorough and complete manner.

The National Academy of Sciences, among others, has recommended abandoning the affirmative defense of inequitable conduct altogether in an effort to reduce litigation costs associated with the subjective questions involved.<sup>173</sup> Supporters of this idea point out that only 2% of patents are litigated anyway.<sup>174</sup> \*410 Others have commented the defenses of patent invalidity and inequitable conduct are redundant; a study by Nolan-Stevaux indicated that in 89% of district court cases between 1995 and 2004 where inequitable conduct was found, the patent at issue was also found invalid.<sup>175</sup> Finally, some argue the opposition-like procedures in the current congressional reform proposals would essentially create an inter parte examination process, taking away one of the primary policy rationales for the inequitable conduct doctrine.<sup>176</sup>

Abandoning inequitable conduct as a claim would certainly simplify patent litigation in some respects, but even with the advent of an opposition-type system, the doctrine serves valuable purposes. Although Nolan-Stevaux’s statistics imply inequitable conduct is found predominantly in cases where the patent was also invalid, her analysis ignored whether, in each case, the misconduct had any relation to the court’s decision to invalidate the patent.<sup>177</sup> Importantly, an opposition system alone would not expose cases of fraud on the Patent Office that are based on information available only to the applicant. For example, in *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.*,<sup>178</sup> without the inequitable conduct doctrine, evidence that the experiments were never actually performed would not have been available to the court, and an invalid patent would have been allowed to stand. The doctrine does serve a valuable function, but reform needs to dictate heightened evidentiary standards for challengers and a more predictable framework for patent applicants.

Other commentators have proposed maintaining or even lowering the current inequitable conduct standards to combat a perceived high rate of improperly issued patents, arguing there is no inequitable conduct “plague” at all.<sup>179</sup> Several analysts feel the inequitable conduct defense is necessary to help police the system, hypothesizing that an allegedly high rate of patent applications that issue indicates a high rate of invalid patents<sup>180</sup> and that misconduct by applicants has caused the problem. However, as the National Academies report points out, estimates of patent issuance rates are based on various imperfect assumptions, and even an accurate accounting would be a suspect measure of patent validity.<sup>181</sup> While a constant increase in patent issuance rates over time might be reason for concern, the Patent Office has had a steadily declining rate of patent issuance since 1998, and \*411 any increases could be caused by other factors.<sup>182</sup> There is simply no indication the patent

system needs an expansion of the inequitable conduct doctrine to keep patent quality high--improperly issued patents are discovered through invalidity challenges without the need for subjective evaluations. Additionally, most advocates of the "current" standards weighed in before the recent expansion of the Federal Circuit's analytical standards for materiality and intent. Even prior to the recent spate of Federal Circuit decisions, the "plague" was hard to ignore--Nolan-Stevaux's analysis showed that from 1995 to 2004, frivolous claims of inequitable conduct were pervasive, as in 75% of cases courts found no inequitable conduct either at summary judgment or after trial.<sup>183</sup> As she concluded, "the patent system often enables potentially infringing parties to attack valid patents by alleging inequitable conduct where none exists."<sup>184</sup>

To address this pressing problem, Congress should reform the law by setting higher standards and clearly defining the test. Not only has the current change in the Federal Circuit's stance given rise to concerns about the return of a "plague," but some of the original justifications for a strict doctrine have been muted. "[S]ince the creation of the inequitable conduct doctrine by the courts, other safeguards have been adopted by Congress and the PTO to support the integrity of the patent system."<sup>185</sup> Such changes have included "third-party and PTO-initiated re-examination on withheld prior art, publication of pending applications, and third-party access to pending prosecution papers and the ability to submit material information."<sup>186</sup> Coupled with the proposed opposition-type rules,<sup>187</sup> the patent prosecution process is no longer exclusively an ex parte proceeding, so there is less of a need for an expansive inequitable conduct standard. Competitors and challengers can make their arguments known long before litigation arises and have conflicts determined by technical experts at the Patent Office rather than by federal judges. Not only would the opposition process save potential litigation time and expense, but it should also save competitors the time and risk associated with developing competing or infringing goods without a firm grasp on the status of the patent in question. In addition, Congress has stepped up protections for the patent system in other ways, including the laws of "antitrust, unfair competition, common law fraud, and tortious interference."<sup>188</sup> Tightening up the inequitable conduct \*412 analytical framework will not destroy the integrity of the patent system, but instead will foster open communication between applicants and the PTO.

## V. Navigating the Course--Conclusions

In recent years, the Federal Circuit has relaxed the inequitable conduct doctrine's standards, risking a return to the "plague" of inequitable conduct claims prevalent in the 1980s. The constantly shifting standards leave patent applicants and prosecutors to guess how best to comply with their duty of disclosure and make it easier for challengers to defeat even valid patents. Congress needs to address these problems by defining clear, predictable rules for alleging and proving inequitable conduct. Effective reform will include measures that require inequitable conduct to be pled with particularity, clearly define the materiality and intent standards, require a showing the misconduct caused patent issuance before sanctions are imposed, and give courts discretion in fashioning suitable remedies. New legislation should not encompass the inequitable conduct portion of Patent Reform Act of 2007. Instead, Congress create legislation which more comprehensively addresses problems facing patent applicants, prosecutors, and litigators. Such changes are necessary to support a healthy and robust domestic patent system.

### Footnotes

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<sup>1</sup> U.S. Const. art. I, §8, cl. 8.

<sup>2</sup> 1 Nat'l Sci. Bd., Nat'l Sci. Found., Science and Engineering Indicators 2008, at 6-31 (2008), available at <http://www.nsf.gov/statistics/seind08/pdf/volume1.pdf>.

<sup>3</sup> S. Comm. on the Judiciary, The Patent Reform Act of 2007, S. Rep. No. 110-259, at 4 (2008).

- 4 Kelvin King, *The Value of Intellectual Property, Intangible Assets and Goodwill*, World Intellectual Property Organization, [http://www.wipo.int/sme/en/documents/value\\_ip\\_intangible\\_assets.htm](http://www.wipo.int/sme/en/documents/value_ip_intangible_assets.htm) (last visited Feb. 28, 2009).
- 5 Fed. Trade Comm'n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* ch. 1, at 1 (2003), available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf> [hereinafter FTC] (“Patent policy encourages prospective inventors to invest time and money in inventions ....”).
- 6 Johnson & Johnson 2007 Annual Report 41 (2008), available at <http://www.jnj.com/connect/about-jnj/publications/> (follow “2007 Annual Report (PDF Format - Recommended for printing)” hyperlink); Cisco Systems, Inc. 2007 Annual Report 26 (2008), available at [http://www.wipo.int/sme/en/documents/value\\_ip\\_intangible\\_assets.htm](http://www.wipo.int/sme/en/documents/value_ip_intangible_assets.htm).
- 7 FTC, *supra* note 5, ch. 1, at 1-2 (noting that patent’s exclusive rights “allow inventors to realize returns sufficient to encourage the initial investments”).
- 8 *Perspectives on Patents: Hearing Before the Subcomm. on Intellectual Property of the S. Comm. on the Judiciary, 109th Cong. 12* (2005) (statement of Jon W. Dudas, Director, United States Patent and Trademark Office).
- 9 Law Practice Mgmt. Comm., *Am. Intellectual Prop. Law Ass’n, Report of the Economic Survey 2007*, at 25 (2007).
- 10 *Id.*
- 11 *Id.*
- 12 See *Comm. on Intellectual Prop. Rights in the Knowledge-Based Econ., Nat’l Research Council, A Patent System for the 21st Century* 32 (Stephen A. Merrill et al. eds., 2004), available at <http://www.nap.edu/html/patentsystem/0309089107.pdf> [hereinafter NRC] (“The number of patent lawsuits settled in or disposed by federal district courts doubled between 1988 and 2001, from 1,200 to nearly 2,400.”).
- 13 Merriann M. Panarella, *Stemming the Patent Litigation Tide, Med. Device & Diagnostic Indus.*, Mar. 2004, available at <http://www.devicelink.com/mddi/archive/04/03/004.html> (last visited Feb. 28, 2009).
- 14 NRC, *supra* note 12, at 7.
- 15 NRC, *supra* note 12, at 122.
- 16 Peter A. Jackman, “Inequitable Conduct” Standard for Patent Suits Is Heightened, 16 *Legal Opinion Letter* No. 17 (Washington Legal Found., Washington, D.C.), June 16, 2006, available at <http://www.wlf.org/upload/061606jackman.pdf>.
- 17 *Id.*
- 18 *Id.*
- 19 See Katherine Nolan-Stevaux, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 *Berkeley Tech. L.J.* 147, 148 (2005) (stating there is a “practice of asserting a defense of inequitable conduct, regardless of the merits of the defense in a given case”).

20 See *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 244 (1933).  
The governing principle is “that whenever a party who, as actor, seeks to set the judicial machinery in motion and obtain some remedy, has violated conscience, or good faith, or other equitable principle, in his prior conduct, then the doors of the court will be shut against him in limine; the court will refuse to interfere on his behalf, to acknowledge his right, or to award him any remedy.”  
Id. (quoting 1 John Norton Pomeroy & John Norton Pomeroy, Jr., *A Treatise on Equity Jurisprudence* §397 (4th ed. 1918)).

21 Id. at 246-47.

22 Id. at 244.

23 Id. at 247.

24 *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945).

25 Id. at 816.

26 37 C.F.R. §1.56 (2009).

27 Id.

28 Linda K. McLeod, *Knew or Should Have Known, Reckless Disregard for the Truth, and Fraud Before the Trademark Office*, 34 *AIPLA Q.J.* 287, 291 (2006).

29 37 C.F.R. §1.56(a).

30 Nolan-Stevaux, *supra* note 19, at 150.

31 *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995).

32 Id.

33 Nolan-Stevaux, *supra* note 19, at 151.

34 *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1364 (Fed. Cir. 1984).

35 NRC, *supra* note 12, at 121.

36 See Nolan-Stevaux, *supra* note 19, at 151 (stating that inequitable conduct during prosecution invalidates the entire patent).

37 See, e.g., *Monsanto Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229, 1242-43 (Fed. Cir. 2008); *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1229-30 (Fed. Cir. 2007), cert. denied, 128 S. Ct. 2938 (2008).

38 Robert C. Scheinfeld & Parker H. Bagley, Lessons from Recent Findings of Inequitable Conduct, 229 N.Y.L.J., May 28, 2003, at 3, available at <http://www.bakerbotts.com/infocenter/publications/detail.aspx?id=35970f92-9a01-40f6-9591-c5bb5f0b68b4>.

39 35 U.S.C. §285 (2006).

40 See NRC, supra note 12, at 122 (listing as among the “severe” consequences of inequitable conduct the possibility the patentee will be exposed to an antitrust claim); Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 174 (1965) (holding inequitable conduct may serve as the basis of an antitrust claim under the Sherman Act).

41 See Williams v. Purdue Pharma Co., No. Civ.A. 04-451 (EGS), 2004 WL 1219061, at \*1 (D.D.C. June 3, 2004).

42 Schecher v. Purdue Pharma L.P., 317 F. Supp. 2d 1253, 1255 (D. Kan. 2004).

43 Scheinfeld & Bagley, supra note 38; NRC, supra note 12, at 122.

44 35 U.S.C. §32 (2006); see, e.g., Klein v. Peterson, 866 F.2d 412 (Fed. Cir. 1989) (affirming attorney’s two-year suspension and five-year probation from practicing before the Office); Jeanne C. Curtis et al., Litigation Issues Relevant to Patent Prosecution--The Defense of Inequitable Conduct, in Fundamentals of Patent Prosecution 2007: A Boot Camp for Claim Drafting & Amendment Writing 229 (PLI Course Handbook Order No. 11260, 2007) (“A patent attorney or agent may also be sanctioned by the Patent Office, including suspension, for violating his/her duty of candor and good faith.”); Scheinfeld & Bagley, supra note 38 (noting “breaches of the duty of candor” can “have far-reaching consequences,” including disciplinary action against the responsible attorney or agent who is registered to practice before the Patent and Trademark Office”).

45 See NRC, supra note 12, at 122 (stating concerns about reputation should deter inequitable conduct).

46 Nolan-Stevaux, supra note 19, at 157-58.

47 35 U.S.C. §282 (2006).

48 37 C.F.R. §1.56(a) (2009).

49 See Robert L. Harmon, Patents and the Federal Circuit 1069 (BNA 8th ed. 2007).

50 Nolan-Stevaux, supra note 19, at 156.

51 See Daniel E. Fisher, U.S. Patent Office Guest Lecturer Program Needs Participants, Institute (IEEE), Mar. 1, 2000, <http://www.theinstitute.ieee.org/> (follow “more news” hyperlink under “news from around the IEEE”; then follow “Archives” hyperlink; then follow “U.S. Patent Office Guest Lecturer Program Needs Participants” hyperlink) (noting patent examiners “apply their specialized knowledge of their technology area to examine patent applications”).

52 Perspectives on Patents, supra note 8, at 32 (submission of Robert A. Armitage, Senior Vice President and General Counsel for Eli Lilly and Company).

53 Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1454 (Fed. Cir. 1984).

54 Burlington Indus. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed. Cir. 1988).

55 Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 875-77 (Fed. Cir. 1988).

56 See infra Part III.A; Erica Wilson, The Resurgence of Inequitable Conduct as a Defense to Patent Infringement (The Special Care Required When Submitting Affidavits to the PTO), *Intell. Prop. Q. Newsl.* (Morrison & Foerster LLP), Spring 2007, at 3, 4, available at <http://www.mofo.com/docs/pdf/IPNewsletter0507.pdf> (“In the wake of the Kingsdown decision and the PTO’s changes to its definition of what constitutes material information, ‘inequitable conduct’ came to be viewed as a disfavored defense that is difficult to prove.”).

57 37 C.F.R. §1.56(a) (1991).

58 Digital Control Inc. v. Charles Mach. Works, 437 F.3d 1309, 1316 (Fed. Cir. 2006).

59 37 C.F.R. §1.56(b) (1992).

60 U.S. Patent & Trademark Office, Manual of Patent Examining Procedure (MPEP) §2001.04 (8th ed., rev. 7, 2008).

61 Digital Control, 437 F.3d at 1315 (citing *Am. Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1363 (Fed. Cir. 1984)).

62 *Id.* at 1316.

63 *Id.*

64 Digital Control Inc. v. Charles Mach. Works, 437 F.3d 1309, 1316 (Fed. Cir. 2006).

65 McKesson Info. Solutions, Inc. v. Bridge Med., Inc., 487 F.3d 897, 912 (Fed. Cir. 2007).

66 Digital Control, 437 F.3d at 1315.

67 *Id.* at 1314-15.

68 *Id.* at 1315 (quoting *Am. Hoist & Derick Co. v. Sowa & Sons*, 725 F.2d 1350, 1362-63 (Fed. Cir. 1989)).

69 *Id.* at 1316.

70 See *id.* (stating a material misstatement or omission under any of the tests makes that conduct material under the new standard).

71 *Id.*

72 Digital Control Inc. v. Charles Mach. Works, 437 F.3d 1309, 1315-16 (Fed. Cir. 2006) (quoting *Am. Hoist*, 725 F.2d at 1363).



73 Id. at 1316.

74 Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp., 424 F.3d 1347, 1359-60 (Fed. Cir. 2005).

75 Old Town Canoe Co. v. Confluence Holdings Corp., 448 F.3d 1309, 1322 (Fed. Cir. 2006).

76 Novo Nordisk, 424 F.3d at 1359-60.

77 Id. at 1362.

78 Purdue Pharma L.P. v. Endo Pharm. Inc., 438 F.3d 1123, 1133 (Fed. Cir. 2006).

79 McKesson Info. Solutions, Inc. v. Bridge Med., Inc., 487 F.3d 897, 911, 924-25 (Fed. Cir. 2007).

80 Refac Int'l, Ltd. v. Lotus Dev. Corp., 81 F.3d 1576, 1582-83 (Fed. Cir. 1996) (citing Paragon Podiatry Lab., Inc. v. KLM Labs., Inc., 984 F.2d 1182, 1191 (Fed. Cir. 1993)).

81 See Refac, 81 F.3d at 1578-85 (finding the affidavit omitted material information for failure to disclose that the affiant had been employed by inventors' company for eight weeks and had some knowledge of the claimed invention); Paragon, 984 F.2d at 1190-92 (reasoning there was an intent to deceive when affiants were stockholders in the company to which the application was assigned).

82 Monsanto Co. v. Bayer Bioscience N.V., 514 F.3d 1229, 1239-40 (Fed. Cir. 2008).

83 Digital Control Inc. v. Charles Mach. Works, 437 F.3d 1309, 1318 (Fed. Cir. 2006).

84 NRC, *supra* note 12, at 122; see also Molins PLC v. Textron, Inc., 48 F.3d 1172, 1184 (Fed. Cir. 1995) (stating that “‘burying’ a particularly material reference in a prior art statement containing a multiplicity of other references can be probative of bad faith.” (citing MPEP §2004, P 13 (4th ed., rev. 5, 1981))); FTC, *supra* note 5, ch. 5, at 11 n.73-74 and accompanying text.

85 See Digital Control, 437 F.3d at 1318 (stating misstatements can be material even if the patent would have issued regardless of the misstatements).

86 Gen. Electro Music Corp. v. Samick Music Corp., 19 F.3d 1405, 1412 (Fed. Cir. 1994).

87 Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 819 (1945).

88 PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc., 225 F.3d 1315, 1321-22 (Fed. Cir. 2000).

89 Ulead Sys., Inc. v. Lex Computer Mgmt. Corp., 351 F.3d 1139, 1146 (Fed. Cir. 2003).

90 MPEP §2001.05 (8th ed., rev. 7, 2008).

91 S. Comm. on the Judiciary, The Patent Reform Act of 2007, S. Rep. No. 110-259, at 32 n.152 (2008).

92 S. Rep. No. 110-259, at 32 n.152.

93 NRC, *supra* note 12, at 122.

94 *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180-81 (Fed. Cir. 1995).

95 *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988).

96 See, e.g., *Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984).

97 *Kingsdown*, 863 F.2d at 876.

98 James E. Hanft & Stacey S. Kerns, The Return of the Inequitable Conduct Plague: When “I Did Not Know” Unexpectedly Becomes “You Should Have Known,” 19 No. 2 *Intell. Prop. & Tech. L.J.* 1, \*1 (2007) (emphasis added).

99 *Braun, Inc. v. Dynamics Corp. of Am.*, 975 F.2d 815, 822 (Fed. Cir. 1992).

100 *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006) (quoting *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 693 (Fed. Cir. 2001)).

101 NRC, *supra* note 12, at 122.

102 See, e.g., *eSpeed, Inc. v. Brokertec USA, L.L.C.*, 480 F.3d 1129, 1134-35, 1138 (Fed. Cir. 2007) (“An inference of intent may arise where material false statements are proffered in a declaration or other sworn statement submitted to the PTO.”).

103 *Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1357, 1361-62 (Fed. Cir. 2005).

104 *Id.* at 1362.

105 *Id.* at 1366.

106 *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1184 (Fed. Cir. 2006).

107 *Id.* at 1191.

108 See *id.* at 1194 (presenting five declarations, four of which had significant association with the assignee, and failing to state declarants’ affiliation gave the misleading impression of a “broad consensus of scientific support” to overcome a particular reference).

109 See *id.* at 1193 (“[O]nce the examiner discounts an affidavit for bias, the applicant is deemed to be on notice that a disinterested

affidavit is required. The evidence here indicates that the examiners previously discounted the opinions of those connected to Ferring because the examiners found Ferring to have a substantial interest in the patent.” (citation omitted).

110 McKesson Info. Solutions, Inc. v. Bridge Med., Inc., 487 F.3d 897, 914 (Fed. Cir. 2007).

111 Id. at 918.

112 Id. at 916.

113 Purdue Pharma L.P. v. Endo Pharm. Inc., 438 F.3d 1123, 1134-35 (Fed. Cir. 2006).

114 Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348, 1354 (Fed. Cir. 2005) (emphasis added).

115 M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., 439 F.3d 1335, 1341 (Fed. Cir. 2006).

116 McKesson Info. Solutions, Inc. v. Bridge Med., Inc., 487 F.3d 897, 916 (Fed. Cir. 2007) (citing Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348, 1354-55 (Fed. Cir. 2005)).

117 Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1191 (Fed. Cir. 2006) (quoting Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1257 (Fed. Cir. 1997)).

118 Wilson, *supra* note 56, at 5.

119 See MPEP §2001.06 (8th ed., rev. 7, 2008) (stating patentees “have a duty to disclose to the U.S. Patent and Trademark Office all material information they are aware of.”).

120 Ferring, 437 F.3d at 1196 (Newman, J., dissenting).

121 Id.

122 Id. at 1203.

123 McKesson Info. Solutions, Inc. v. Bridge Med., Inc., 487 F.3d 897, 926 (Fed. Cir. 2007) (quoting FMC Corp. v. Manitowoc Co., Inc., 835 F.2d 1411, 1415 (Fed. Cir. 1987)).

124 Id. at 926-27.

125 Compare 37 C.F.R. §1.56(a) (1991) (using a “reasonable examiner” standard as the basis for materiality), with 37 C.F.R. §1.56(b) (1992) (using a prima facie unpatentability or inconsistent statement standard for materiality).

126 FTC, *supra* note 5, ch. 5, at 5.

127 Changes to Information Disclosure Statement Requirements and Other Related Matters, 71 Fed. Reg. 38,808, at 38,810 (proposed

July 10, 2006) (to be codified at 37 C.F.R. pt. 1).

128 Id. at 38,809-10.

129 Id. at 38,810.

130 See id. (“It should be noted that a threshold of twenty documents ... would not require a change in practice for most appellants.”).

131 Id.

132 McKesson Info. Solutions, Inc. v. Bridge Med., Inc., 487 F.3d 897, 920-21, 925 (Fed. Cir. 2007).

133 Though 85% of cases do not reach the twenty document threshold, 15% still do. See Changes to Information Disclosure Statement Requirements and Other Related Matters, 71 Fed. Reg. 38,808, at 38,810 (proposed July 10, 2006) (to be codified at 37 C.F.R. pt. 1). The submission of additional references under McKesson will put many more cases above the twenty document threshold.

134 FTC, supra note 5, ch. 5, at 12.

135 FTC, supra note 5, ch. 5, at 12.

136 See MPEP §2001.06 (8th ed., rev. 7, 2008) (limiting applicants’ duty to disclose to “all material information they are aware of”).

137 Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46,716, 46,742 (proposed Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1).

138 Id. at 46,741.

139 *Tafas v. Dudas*, 541 F. Supp. 2d 805, 814 (E.D. Va. 2008).

140 *Tafas v. Doll*, No. 2008-1352, 2009 WL 723353, at \*1 (Fed. Cir. Mar. 20, 2009).

141 Id. at \*15.

142 S. Comm. on the Judiciary, The Patent Reform Act of 2007, S. Rep. No. 110-259, at 97 (2008).

143 S. Rep. No. 110-259, at 97.

144 Patent Reform Act of 2008, S. 3600, 110th Cong. §123(a) (2008).

145 Howard M. Eisenberg, Patentability Searching, 4 (2000), <http://www.yale.edu/ocr/pfg/guidelines/docs/patentability.pdf>.

- <sup>146</sup> The Coalition for 21st Century Patent Reform, Applicant's Responsibilities 2, [http://www.patentmatter.com/issue/leg\\_proposals/Applicant%20Quality%CC20Submissions%CC20S.%C4%BD5.pdf](http://www.patentmatter.com/issue/leg_proposals/Applicant%20Quality%CC20Submissions%CC20S.%C4%BD5.pdf) (last visited Mar. 3, 2009).
- <sup>147</sup> See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736-37 (2002) (applying prosecution history estoppel to amendments).
- <sup>148</sup> *Winbond Elecs. Corp. v. Int'l Trade Comm'n*, 262 F.3d 1363, 1375-76 (Fed. Cir. 2001).
- <sup>149</sup> *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 926-27 (Fed. Cir. 2007) (Newman, J., dissenting).
- <sup>150</sup> S. Comm. on the Judiciary, *The Patent Reform Act of 2007*, S. Rep. No. 110-259, at 113 (2008).
- <sup>151</sup> Cf. Fed. R. Civ. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.").
- <sup>152</sup> See, e.g., *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499, 2501, 2502 (2007).
- <sup>153</sup> S. Rep. No. 110-259, at 33 n.156.
- <sup>154</sup> *Perspectives on Patents: Post-Grant Review Procedures and Other Litigation Reforms: Hearing Before the Subcomm. on Intellectual Property of the Senate Comm. on the Judiciary, 109th Cong. 7* (2006) (statement of Philip S. Johnson, Chief Patent Counsel, Johnson & Johnson).
- <sup>155</sup> Professional Inventors Alliance, *Limitation of Inequitable Conduct, The PIA Viewpoint*, [http://www.piausa.org/patent\\_reform\\_issues/limitation\\_of\\_inequitable\\_conduct/](http://www.piausa.org/patent_reform_issues/limitation_of_inequitable_conduct/) (last visited Mar. 4, 2009).
- <sup>156</sup> Fed. R. Civ. P. 42(b) (giving courts the discretion to bifurcate counterclaims into separate trials "[f]or convenience, to avoid prejudice, or to expedite and economize").
- <sup>157</sup> Nolan-Stevaux, *supra* note 19, at 160-63.
- <sup>158</sup> Patent Reform Act of 2007, H.R. 1908, 110th Cong. §124(c)(1) (2007); S. Comm. on the Judiciary, *The Patent Reform Act of 2007*, S. Rep. No. 110-259, at 113 (2008).
- <sup>159</sup> S. Rep. No. 110-259, at 113.
- <sup>160</sup> S. Rep. No. 110-259, at 33 n.155; see, e.g., *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1223 (Fed Cir. 2007), cert. denied, 128 S. Ct. 2938 (2008); *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 926 (Fed. Cir. 2007); *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1189 (Fed. Cir. 2006).
- <sup>161</sup> S. Rep. No. 110-259, at 113.
- <sup>162</sup> H. Comm. on the Judiciary, *Patent Reform Act of 2007*, H.R. Rep. No. 110-314, at 18 (2007).

163 Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 876 (Fed Cir. 1988).

164 Perspectives on Patents, supra note 154.

165 The Coalition for 21st Century Patent Reform, supra note 146.

166 Nilssen v. Osram Sylvania, Inc., 504 F.3d 1223, 1243 (Fed Cir. 2007), cert. denied, 128 S. Ct. 2938 (2008).

167 Monsanto Co. v. Bayer Bioscience N.V., 514 F.3d 1229, 1243 (Fed. Cir. 2008).

168 S. Comm. on the Judiciary, The Patent Reform Act of 2007, S. Rep. No. 110-259, at 113-14 (2008) (emphasis added).

169 H. Comm. on the Judiciary, Patent Reform Act of 2007, H.R. Rep. No. 110-314, at 18 (2007).

170 The Coalition for 21st Century Patent Reform, supra note 146.

171 The Coalition for 21st Century Patent Reform, supra note 146 (emphasis added).

172 S. Rep. No. 110-259, at 113 (referring to the Patent Act of 1952, P.L. 82-593).

173 NRC, supra note 12, at 82.

174 See Mark A. Lemley, Rational Ignorance at the Patent Office, 95 Nw. U. L. Rev. 1495, 1501 (2001).

175 Nolan-Stevaux, supra note 19, at 165.

176 See, e.g., Nolan-Stevaux, supra note 19, at 165; Perspectives on Patents, supra note 154.

177 See Nolan-Stevaux, supra note 19.

178 Purdue Pharma L.P. v. Endo Pharm. Inc., 438 F.3d 1123, 1133 (Fed. Cir. 2006).

179 See, e.g., Perspectives on Patents, supra note 8 (statement of Richard C. Levin, Ph.D., President, Yale University).

180 NRC, supra note 12, at 52-53 (citing studies which reported between a 83% and 97% issuance rate for patent applications).

181 NRC, supra note 12, at 53-54.

182 NRC, supra note 12, at 54-55 (“[I]t is possible that the higher cost of obtaining patents has caused firms to be more rigorous in screening inventions for which they file applications, or that greater predictability in the applications of patentability criteria by the

USPTO means that firms are better at weeding out inventions that will not result in granted patents.”).

183 Nolan-Stevaux, supra note 19, at 161-64.

184 Nolan-Stevaux, supra note 19, at 164.

185 NRC, supra note 12, at 122-23.

186 NRC, supra note 12, at 123.

187 Perspectives on Patents, supra note 154.

188 NRC, supra note 12, at 122.