United States Court of Appeals for the Federal Circuit

2007-1109

MONSANTO COMPANY,

Plaintiff-Appellee,

v.

BAYER BIOSCIENCE N.V.,

Defendant-Appellant.

Susan K. Knoll, Howrey LLP, of Houston, Texas, argued for plaintiff-appellee. With her on the brief were Steven G. Spears, Daniel T. Shvodian, and Michelle C. Replogle.

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Appealed from: United States District Court for the Eastern District of Missouri

Judge E. Richard Webber

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Appeal from the United States District Court for the Eastern District of Missouri in case no. 4:00-CV-01915, Judge E. Richard Webber.

DECIDED: January 25, 2008

Before BRYSON, GAJARSA, and DYK, Circuit Judges.

GAJARSA, Circuit Judge.

This is a patent infringement case relating to chimeric genes. Plaintiff-Appellee Monsanto Co. ("Monsanto") brought a declaratory judgment action against Defendant-Appellant Bayer Bioscience N.V. ("Bayer") challenging the validity and unenforceablity of four Bayer patents, U.S. Patent Nos. 5,545,565 ("the '565 patent"), 5,767,372 ("the '372 patent"), 6,107,546 ("the '546 patent"), and 5,254,799 ("the '799 patent"), and asserting that Monsanto's transgenic corn products did not infringe these patents. Bayer appeals a final judgment, issued after jury trial, declaring the asserted claims of the '565 patent invalid and non-infringed. In addition, Bayer appeals the final judgment

of the district court that the four patents are unenforceable for inequitable conduct. We affirm the district court's conclusion that the '565 patent is unenforceable for inequitable conduct and hold that the district court had jurisdiction to declare the '372, '546, and '799 patents unenforceable. Accordingly, we do not reach the other issues raised by Bayer on appeal.

I.

Strains of the bacteria Bacillus thuringiensis ("Bt") produce proteins, known as Bt toxins, that while harmless for humans and most animals, are toxic to certain crop-destroying insects. In the 1980s multiple companies and academic groups took advantage of the newly emergent science of genetic engineering by attempting to insert a gene for Bt toxin into plants through a process known as transformation. The goal was for these genetically engineered plants to express (i.e., produce) a Bt toxin protein in sufficient quantities to make the plants insect-resistant.[1] Difficulties in getting plants to express a full-length Bt toxin gene, which encodes a protein of approximately 130 kD,[2] led researchers to investigate various alternatives. In 1986, Plant Genetic Systems, N.V., a predecessor of Bayer (hereinafter referred to as "Bayer"), succeeded in obtaining plants that expressed a truncated form of a Bt toxin. This shortened protein was produced by transforming the plants with a fragment of a Bt toxin gene that encoded the first part (or N-terminal end) of the toxin, using the bacterium

[1] Background on the science of genetically engineering plants to express Bt toxin can be found in our previous opinion Mycogen Plant Science, Inc. v. Monsanto Co., 243 F.3d 1316, 1324 (Fed. Cir. 2001).

[2] kD, or kilodalton, is a measure of the molecular weight of a protein.

Agrobacterium tumefaciens ("Agrobacterium"), a known system for plant transformation.[3]

The four patents involved in the present suit relate to this invention. The '565 patent claims chimeric genes[4] comprising (a) a truncated Bt toxin gene encoding an approximately 60 kD to 80 kD Bt toxin of a specific amino acid sequence,[5] and (b) the regulatory region of a gene "naturally expressed in plant cells,"[6] which enables the gene to be transcribed in plants, i.e., a "plant promoter," where the Bt toxin gene is under the control of the plant promoter.[7] The '372 patent, '546 patent, and the '799 patent are

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[3] When Agrobacterium infects certain plant cells, it integrates a part of its DNA, the T-DNA plasmid, into the genome of the plant. To genetically engineer a plant using the Agrobacterium transformation method, the foreign DNA of interest is first introduced into the T-DNA plasmid. Then the plant is infected with Agrobacterium containing the modified T-DNA, leading to the introduction of the foreign segment into the plant cell genome. See In re Goodman, 11 F.3d 1046, 1048 (Fed. Cir. 1993). When the encoding region of the foreign gene is linked to a regulatory region recognized by the plant cell machinery, the transformed plant cell will be able to express the protein encoded by the foreign gene.

[4] A chimeric gene is an artificial (i.e., human made) gene created by linking together separate segments of natural or synthetic DNA from different sources.

[5] Not all Bt toxins have identical amino acid sequences. The sequence limitation, added during the prosecution to overcome rejection, limits Bayer's invention to chimeric genes encoding a specific variant of Bt toxin.

[6] The specification defines a gene naturally expressed in plants to include both those genes that are originally part of a plant's genome and those genes which are introduced by agents such as bacteria and produce RNA or protein in the absence of human intervention. '565 patent col.9 ll. 52-57. One plant promoter disclosed in the specification is the promoter of the T-DNA nopaline synthase gene, the "nos promoter."

[7] Claims 2, 5, and 8 of the '565 patent were at issue, with claim 5 being representative. In independent form it recites:

> 5. A chimeric gene comprising:
>
> (1) a DNA fragment encoding an insecticidal Bacillus thuringiensis Bt2 toxin of about 60 to about 80 kD, wherein said Bt2 toxin comprises the amino acid sequence ID No. 1 from amino acid position 1 to amino acid position 725; and

directed towards various other aspects of the technology including plant cells and plants that produce the insecticidal protein, and methods of transforming plants with the chimeric genes.

Monsanto sells a genetically modified corn product MON810 that expresses a Bt toxin with the same amino acid sequence claimed by Bayer. In December 2000, Monsanto filed a declaratory judgment action in the Eastern District of Missouri seeking a declaration that its product did not infringe the '565, '372, '546, and '799 patents and that these patents were invalid and unenforceable. Bayer counterclaimed alleging infringement of certain claims in each patent. The district court initially granted summary judgment to Monsanto, holding that all four patents were unenforceable due to inequitable conduct, that certain patent claims were invalid, and that the '565 patent was not infringed. Bayer appealed to this court. We reversed the trial court's claim construction as to the term "Bt2 toxin" and vacated the unenforceability and invalidity judgments. Monsanto Co. v. Bayer BioScience N.V., 363 F.3d 1235 (Fed. Cir. 2004) (Monsanto I). In particular, we held that the summary judgment of unenforceability based on inequitable conduct during the prosecution of the '799 patent was improper because there were material facts in dispute, and we concluded that the district court erred in giving collateral estoppel effect to an earlier case between predecessors of the parties in this case and basing its invalidity findings on this estoppel.

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(2) a promoter region of a gene naturally expressed in plant cells, wherein said DNA fragment is under the control of said promoter region.

'565 patent col.115. Dependent claim 12 adds a limitation that the plant promoter come from one of three genes, including the nopaline synthase gene. Id.

On remand, Bayer dismissed all claims that MON810 infringed the '799, '372, and '546 patents and filed a Statement of Non-Liability as to these patents. Accordingly, when the case proceeded to trial, only the '565 patent was at issue. The jury found the asserted claims of the '565 patent not infringed and invalid for obviousness and prior invention by Monsanto.

Subsequently, the district court held a four-day bench trial on inequitable conduct. In a 99-page opinion, the district court found materiality and intent for two separate acts relating to the '565 patent and concluded that inequitable conduct made the '565 patent unenforceable. Monsanto v. Bayer Bioscience N.V., No. 400cv01915, slip. op. (E.D. Mo. Aug. 28, 2006) (Monsanto II). The court also found inequitable conduct in the prosecution of the '799, '372, and '546 patents and accordingly held these patents unenforceable. Id. at 95. Bayer appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

In the current appeal, Bayer argues that the district court erred in claim construction, that allegedly prejudicial evidence was admitted during the jury trial, that there was insufficient evidence to sustain the jury findings of prior invention and obviousness, that the district court erred in finding the '565 patent unenforceable for inequitable conduct, and that the district court lacked jurisdiction to find the '799, '372, and '546 patents unenforceable.

Because we affirm the district court's holding that the '565 patent is unenforceable for inequitable conduct, we need not reach the other issues raised by Bayer relating to the jury findings of invalidity and non-infringement of the patent. See

eSpeed, Inc. v. Brokertec USA L.L.C., 480 F.3d 1129, 1138-39 (Fed. Cir. 2007). Accordingly, we review only the district court's inequitable conduct holdings.

II.

When this Court reviews an inequitable conduct determination, "[w]e review the district court's findings on the threshold issues of materiality and intent for clear error." Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1365 (Fed. Cir. 2007). Accordingly, "the district court's determination will be reversed only if there is a 'definite and firm conviction' that a mistake has been made." Id. The ultimate decision on inequitable conduct is reviewed for abuse of discretion. On appeal, Bayer does not challenge the ultimate discretionary determination. Therefore, we review here only whether there was clear error in the district court's underlying materiality and intent findings.

To hold a patent unenforceable for inequitable conduct, a district court must find by clear and convincing evidence that a patent applicant breached its duty of candor and good faith to the United States Patent and Trademark Office ("PTO") by failing to disclose material information, or submitting false material information, with an intent to deceive the PTO. Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs. Ltd., 394 F.3d 1348, 1351 (Fed. Cir. 2005); Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 872 (Fed. Cir. 1988) (internal citations omitted); see also Monsanto I, 363 F.3d at 1239 (explaining that inequitable conduct can be found when the "applicant omitted or misrepresented material facts with the intention of misleading or deceiving the patent examiner"). Once the requisite levels of materiality and intent have been proven, a district court "must balance the equities to determine whether the patentee

has committed inequitable conduct that warrants holding the patent unenforceable." Monsanto I, 363 F.3d at 1239.

A.

During the prosecution of the '565 patent, Bayer disclosed as prior art an abstract by Dr. Wayne Barnes entitled "A Bifunctional Gene for Insecticide and Kanamycin Resistance" (the "Barnes Abstract") that had been prepared in 1985 for a large scientific conference at which Barnes had made a presentation by displaying a poster presenting his findings (the "Barnes Poster"). The abstract read, in relevant part:

> We have found that the second half of the Bacillus thuringiensis toxin gene is dispensable for the expression of an active insecticide. Not only may it be deleted, the second half of the gene may be replaced by the codons of the NPTII kanamycin resistance from Tn5, and both activities are expressed. . . .
>
> We have tailored transcriptional control signals from the [Agrobacterium] T-DNA of pTiT37 so that this fused gene may be inserted in the place of the nopaline synthase codons adjacent to the right border signal from T-DNA. This plant gene should express the insecticide and kanamycin resistance from the same promoter. . . .

Bayer's application, as amended following an initial rejection, claimed any chimeric gene comprising a plant promoter linked to a truncated Bt toxin gene encoding a 60-80 kD N-terminal fragment of a Bt toxin, in which the chimeric gene could be expressed in the cell as an insect-controlling amount of Bt toxin. Narrower, dependent claims, akin to the claims that ultimately issued, specified that the chimeric gene must encode a Bt toxin with a specified amino acid sequence.[8] In addition, the application

[8] The claims which ultimately issued as the '565 patent differ from these preliminary claims, even those that are sequence specific, in that they do not require that the Bt toxin be expressed in plant cells at an insect-controlling amount, but only that the Bt toxin gene be "under the control of" the plant promoter. Bayer did not object to

claimed chimeric genes encoding the Bt toxin fragment fused to a selectable marker protein. Dependent claims included limiting the selectable marker protein to neomycin phosphotransferase ("NTP-II"), an enzyme that provides resistance to the antibiotic kanamycin, and limiting the "plant promoter" to the nos promoter, which is the promoter region from the T-DNA nopaline synthase gene.

On March 21, 1994, the Examiner rejected all claims as obvious over various prior art references including the Barnes Abstract. In particular, the Examiner noted that the Barnes Abstract

> provided motivation to genetically engineer plant cells with a truncated Bt crystal gene rather than using the full length sequence. In the absence of unexpected results it was obvious that a truncated version of the Bt crystal protein would result in plants and plant cells which were insecticidal since the art taught that only the N-terminal protein of the Bt protein, i.e. the portion used by Applicants, was sufficient for insecticidal activity. Furthermore, fusion proteins for truncated Bt. crystal proteins with NPT-II were known as taught by Barnes.

The claims were also rejected for lack of enablement. The Examiner noted that the prior art showed that "expression of [Bt] toxin genes in a plant cell is highly unpredictable" and concluded that "[i]n view of the unpredictability of expression of foreign genes . . . it does not appear that any Bt toxin protein would be effective in plant cells against any species of insect. Consequently, Applicants broader claims are not enabled."

In reply to the office action, Bayer addressed both rejections. In order to overcome the Barnes reference, Bayer argued:

> Barnes et al. fails to identify which Bt. toxin gene should be utilized and also fails to show that the fusion gene would work in plants. Also, if the

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the district court's holding and jury instruction that reduction to practice of the '565 invention did not require making plants which expressed an insecticidal Bt toxin.

> "second half" of the Bt2 gene would be deleted, as Barnes et al. suggests, the remaining part would encode a protein of 576 amino acids, which is not toxic. Moreover, the Barnes et al. reference is not enabled since it is stated therein that the fused gene "may" be inserted into T-DNA and that the plant gene "should" express the insecticide and kanamycin resistance from the same promoter. But no concrete evidence is provided.

On the enablement issue, Bayer argued that "[t]he problem of the unpredictability of expression of foreign genes in plants, that the Examiner purports to exist, has actually been solved by the present invention by providing truncated Bt genes. Any protein expressed in a plant, by inserting a DNA encoding a truncated Bt protein will inherently possess toxicity . . . , and thus the plants will be toxic to target insects." (emphasis added).

Although Bayer disclosed the Barnes Abstract during patent prosecution, it did not disclose the notes taken by one of its employees, Dr. Celestina Mariani, regarding the Barnes Poster, to which the abstract was in reference, nor the information contained in the notes. Mariani had attended the conference and personally viewed Barnes' poster. She explained in her deposition, which was presented at trial, that the notes were made while in front of the poster and included copies of "the same schemes that were presented on the poster." Monsanto II, slip op. at 19 (quoting Mariani's deposition testimony ("Mariani depo.")). The poster contained much more information than the abstract itself. Id. at 24. In the deposition, Mariani carefully and extensively described the content of her handwritten notes. Stepping through the figures and accompanying text, she explained that her notes illustrated that Barnes disclosed in his poster that he had (a) truncated a Bt toxin gene at or near the restriction enzyme site xho and discovered that this gene fragment encoded a N-terminus 67 kD truncated Bt toxin

which retained toxicity; (b) created a chimeric gene which encoded a fusion of this truncated Bt toxin protein and the NPT-II protein; (c) expressed this fusion protein in a bacterial system and demonstrated that the expressed protein provided kanamycin resistance and was toxic to insects when applied to plants "in drops"; and (d) inserted the gene for this fusion protein into an Agrobacterium T-DNA plant expression vector, creating a chimeric gene comprising the nos promoter, the Bt toxin gene fragment encoding a 67 kD toxin, and the NPT-II gene. Id. at 19-24 (quoting Mariani depo.). Mariani's notes also stated that the chimeric construct was "not toxic if it is in leaves." Id. at 22 (quoting Mariani depo.). She explained in her deposition, "I must assume that 'in leaves' then means they have done plant transformation, but I cannot remember exactly, to be honest." Id. at 22 (quoting Mariani depo.). But she emphasized that the construct had been created and that the Barnes group "surely w[as] busy with introducing in plants this cassette" since otherwise there would have been no reason to make the construct in the Agrobacterium T-DNA system. Id. at 24 (quoting Mariani depo.). The district court found that Mariani's testimony demonstrated that she remembered "a great deal about the notes" and was clearly and articulately able to describe the contents of the Barnes Poster as detailed in the notes. Id. at 18.[9]

The Mariani notes were "widely circulated" among Bayer's Bt group. Dr. Wouter Meulemanns worked in the intellectual property department at Bayer and was responsible for the prosecution of the four patents at issue. Id. Meulemanns admitted that he saw Mariani's notes during the prosecution of the '565 patent and remembers

[9] At trial Mariani was much less forthcoming about the content of her notes than she had been in the deposition. The district court, however, found her initial deposition testimony more credible. Monsanto II, slip op. at 97. There is nothing clearly erroneous in this credibility finding.

talking to Mariani about the Barnes Poster and her notes. He conceded that "if [the Mariani] notes would add anything of reliable information which could add to the abstract, that could be important" to a patent examiner. Id. at 17-18 (quoting Meulemanns depo.). However, Meulemanns stated that Mariani was unable to remember "anything" about the presentation or poster during their conversation.

The district court, in its memorandum and order following the inequitable conduct bench trial, carefully reviewed all of this evidence, quoting extensively from the testimony of both Meulemanns and Mariani. The court found Meulemanns' testimony to stand in "sharp contrast" to Mariani's detailed deposition testimony and determined that Meulemanns was not credible in claiming not to have known nor understood the content of the notes despite having discussed them with Mariani. And after quoting at length from Dr. Mariani's deposition testimony, the district court concluded:

> [I]t is very obvious that the poster notes, if they were disclosed to the patent examiner, which they were not, would stand in sharp contradiction to the Bayer argument before the patent examiner . . . . The Court finds from all of the evidence in the case, that Bayer had a duty of candor and good faith to disclose the Mariani notes and intentionally withheld the information from the United States Patent Office examiner in the prosecution of the '565 patent with intention to deceive the PTO examiner.

Id. at 24.

These findings were made in the section of the district court's opinion entitled "Findings of Fact." In the section entitled "Discussion" the district court returned to the question of the materiality of the Mariani notes. The court explained:

> The Court will not repeat the lengthy Mariani recitation from above, but it is clear that the Barnes notes coded for the same 67 Kd toxic protein Bayer wanted to claim, that the Barnes gene was 3.4 kb for the full length, that because of the identified xho site, it would be easy to determine the identity of the Bt gene being used, and the chimeric gene used was toxic to insects by the drop. There is a substantial likelihood that a reasonable

> examiner would have considered the Barnes notes important in deciding whether to allow the application to issue as a patent. . . . The Barnes notes by themselves withheld by Bayer from the PTO examiner, if disclosed, would establish a prima facie case of unpatentability of Bayer's claims under the '565 patent.

Id. at 97-98. Accordingly, the court concluded that "by clear and convincing evidence for all of the reasons cited in this opinion," Bayer made "a deliberate decision to withhold the known highly material reference with the specific intent to deceive or mislead the PTO examiner." Id. The court emphasized that in reaching this determination, it was relying on "all of the findings of fact stated in this opinion," not just those in the discussion section. Id. at 92.

The district court also found by clear and convincing evidence that Bayer's representation to the PTO that unpredictability of gene expression had been solved was false and misleading and was submitted to the PTO examiner with the specific intent to deceive the PTO. Id. at 96.

B.

Information is material for the purposes of an inequitable conduct determination if "'a reasonable examiner would have considered such [information] important in deciding whether to allow the parent application.'" Digital Control Inc. v. Charles Mach. Works, 437 F.3d 1309, 1314 (Fed. Cir. 2006) (quoting Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1363 (Fed. Cir. 2003)). "In evaluating materiality, this court has consistently referred to the standard set forth in PTO Rule 56." Purdue Pharma L.P. v. Endo Pharms., Inc., 438 F.3d 1123, 1129 (Fed. Cir. 2006). Rule 56 defines material information as:

> information that is not cumulative to information already of record or being made of record in the application, and that
>
> (1) establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
> (2) . . . refutes, or is inconsistent with, a position the applicant takes in:
> (i) Opposing an argument of unpatentability relied on by the Office, or
> (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56. A misstatement or omission that is material under the Rule 56 standard is considered material for the purposes of the inequitable conduct inquiry. Digital Control Inc., 437 F.3d at 1316.[10]

Bayer argues that the "sole basis" for the district court's determination that the Mariani notes were material was the conclusion in one sentence of the discussion section that the Barnes construct "coded for the same 67 kD toxic protein Bayer wanted to claim" and "that because of the identified xho site it would be easy to determine the identity of the Bt gene being used." Bayer argues that these findings were clearly erroneous because they were based on the unsupported speculation that Barnes was using the identical species of Bt toxin as Bayer, and that without this "erroneous finding of fact, there can be no materiality." We disagree.

To begin, Bayer is correct that there is nothing in the record which would support a finding that the Bt toxin used by Barnes was identical to the Bt toxin claimed in the

[10] Although all misstatements or admissions that satisfy Rule 56 are considered material, the converse is not true: A misstatement or admission can be material for the purposes of showing inequitable conduct even if it does not meet the standard for Rule 56 if, in the totality of the circumstances, a reasonable examiner would have considered such information important in deciding whether to allow the parent application. See Digital Control Inc., 437 F.3d at 1316 ("[I]f a misstatement or omission is material under the new Rule 56 standard, it is material. Similarly, if a misstatement or omission is material under the 'reasonable examiner' standard or under the older three tests, it is also material.").

issued '565 patent. However, the district court need not have found that Barnes used the identical Bt toxin as Bayer for the Mariani notes to be material. First, at the time of the Examiner's rejection, Bayer was not limiting its claim to one species of Bt toxin protein but was broadly claiming a chimeric construct encoding any 60-80 kD N-terminal fragment of a Bt toxin protein. Thus, any species of chimeric gene created by Barnes within this genus would directly implicate the allowability of Bayer's claims. Cf. Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 971 (Fed. Cir. 2001) (noting that a "genus claim limitation is anticipated by, and therefore not patentably distinct from, a[] . . . species claim"). Second, none of the Examiner's rejections, including his rejections of the sequence specific claims, nor any of Bayer's arguments to overcome these rejections, relied on the exact sequence of Bt toxin used by Barnes. Rather, the issue was whether the Barnes Abstract made Bayer's invention obvious absent unexpected results because Barnes' work with Bt toxin, regardless of the specific species used, provided motivation to genetically engineer plant cells with "a truncated Bt crystal gene" and "taught fusion proteins of truncated Bt crystal proteins with NPT-II." Similarly, the exact sequence of the Barnes protein is irrelevant to the question of whether Bayer's arguments to the PTO interpreting the Barnes Abstract were inconsistent with the information contained in the Mariani notes.[11]

[11] Indeed, at the time, Bayer was arguing that its disclosure of a chimeric gene with one version of a truncated Bt gene was sufficient to enable the genus of all chimeric genes with any truncated Bt toxin gene. See Response to Office Action (Sept. 28, 1994) ("Any Bt protein expressed in a plant, by inserting a DNA encoding a truncated Bt protein will inherently possess toxicity characteristics against its target insect, and thus the plants will be toxic to target insects. It is well within the skill of the person in the art to select a particular Bt protein gene with an observed toxicity to a target insect, truncate the gene and express it to attain resistance against the target

Moreover, Bayer is incorrect that the "sole basis" for the district court's materiality finding was the court's one sentence summary that the Barnes construct coded for the "same 67 kD protein" as Bayer claimed, and the xho site would make it easy to identify. Bayer ignores that the very sentence in the analysis section containing these two statements also repeats the court's critical finding that the Mariani notes showed that the Barnes chimeric gene was toxic when applied to plants as a drop.[12] Furthermore, the district court clearly stated that it was basing its finding of materiality not only on those facts discussed in the analysis section, but also on all the factual findings throughout the opinion.[13] These included finding Mariani's deposition testimony credible and illustrative of the "detail and scope of her notes and of her recollection of them." And the district court incorporated six pages of Mariani's testimony verbatim into its opinion. This testimony established that the Barnes Poster, as recorded in Mariani's notes, disclosed that Barnes had succeeded in making a fusion of the first 67 kD of a Bt protein and NPT II; that this protein could be expressed and displayed kanamycin resistance and toxicity to insects when applied as a drop; and that the gene encoding for this fusion protein had been inserted into a T-DNA plasmid, creating a chimeric gene comprising a plant promoter, the truncated Bt toxin gene, and the NPT-II gene. Based

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insect."). Bayer can therefore not now argue that only those prior art references disclosing the particular Bt toxin described in the specification can be material.

[12] In its opening brief to this court and again in its reply brief, Bayer's quotation of the sentence of the district court's opinion upon which it places primary reliance leaves out this important final clause of the sentence and, by failing to use ellipses, makes it appear that it has quoted the entire sentence. Such misquotation of text, whether inadvertent or purposeful, risks misleading this Court and cannot be of help to the client.

[13] Accordingly, we need not decide whether if the facts repeated in the analysis section had been the only basis for a finding of materiality the district court's finding would constitute clear error.

on Mariani's testimony, the district court found it "very obvious" that the poster notes would stand in "sharp contradiction" to Bayer's argument before the patent examiner, in which Bayer argued that the construct described in the Barnes Abstract was non-toxic and non-enabled.

We see no clear error in these findings. The undisputed evidence established that the arguments Bayer made to the Examiner to overcome the rejection based on the Barnes Abstract cannot be reconciled with the information about the Barnes Poster disclosed in the Mariani notes. First, Bayer argued to the Examiner that he should read the Barnes Abstract's statement that the "second half" of the Bt toxin gene is dispensable literally, as referring to a gene of exactly half the length of the full length gene, and thus one that encoded a 576 amino acid protein, a size known to be too small to be toxic. This was perhaps a plausible, if strained, reading of the Abstract itself. But the interpretation cannot be reconciled with the additional information disclosed about the Barnes Poster in the Mariani notes. Mariani's notes demonstrated that the truncated protein referred to in the abstract was a 67 kD protein with proven insect toxicity.[14] Second, Bayer relied on the use of the word "may" in the Abstract to argue that Barnes had not enabled inserting the Bt toxin/NPT-II fusion gene into Agrobacterium T-DNA because there was no "concrete evidence" that the construct had been made. In contrast, the Mariani notes disclosed that Barnes had in fact created the described T-DNA construct.

In light of these discrepancies between the interpretation of the Barnes Abstract Bayer advocated and the information contained in the Mariani notes, the Mariani notes

[14] A 576 amino acid protein is smaller than 67 kD.

clearly and convincingly "refute[], or [are] inconsistent with," a position the applicant took in opposing the Examiner's argument of unpatentability. 37 C.F.R. § 1.56(2)(i). The notes are therefore material under 37 C.F.R. § 1.56(2)(i). See also Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1234 (Fed. Cir. 2003) ("[M]ateriality is not limited to prior art but embraces any information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent." (quoting GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1274 (Fed. Cir. 2001))).[15] Since the notes meet the standard for materiality under § 1.56(2)(i), there is no clear error in the district court finding the notes material even though a part of the district court's opinion, viewed in isolation, suggests that it may also have reached that conclusion based on an untenable reading of the notes as stating that the Barnes Poster disclosed a gene coding for the same Bt toxin used by Bayer. There is a substantial likelihood that a reasonable examiner would have considered the Mariani notes important in deciding whether to allow the application to issue.

We hold that the Mariani notes are material because they directly contradict arguments Bayer made to the PTO in support of patentability. We do not suggest that all internal documents of potential relevance must be submitted to the PTO as a matter of course. Rather, it is the particular circumstances that render the internal documents material in this case. We need not decide whether, as the district court found, they are also material because the notes by themselves would establish a prima facie case of

[15] That the Mariani notes may have required some explanation by Mariani to be fully understood does not alter their materiality. Rather, it is the information contained in them that makes the notes material and which Bayer, in light of its interpretation of the Barnes Abstract, had an obligation to communicate to the PTO. If an accompanying declaration by Mariani was necessary to make the notes legible, then the duty of candor would require disclosing both the notes and such a declaration.

unpatentability of the '565 patent's claims. But certainly their materiality is augmented by the fact that Mariani's notes demonstrate, in significantly more detail than the Barnes Abstract, that Barnes had already disclosed that a 67 kD N-terminal fragment of a Bt toxin protein retained toxicity either alone or fused to a NPT-II protein and taught a chimeric gene comprising the 67 kD Bt toxin gene and a plant promoter. Bayer was attempting to claim a nearly identical invention—a chimeric gene comprising a gene encoding a 60 to 80 kD Bt toxin protein and a plant promoter. Accordingly, we affirm the district court's finding that the Mariani notes were highly material.[16]

C.

Bayer's failure to disclose the highly material Mariani notes to the PTO during the prosecution of the '565 patent is not sufficient to prove inequitable conduct. Rather, clear and convincing evidence must also establish an intent to deceive the PTO. To prove intent, "the involved conduct, viewed in light of all the evidence, including

[16] In Bayer's reply brief, Bayer argues for the first time that even if its other arguments fail the Mariani notes lack materiality because they would have been "merely cumulative" in light of the prior art reference of a Gene article by Dr. Adang which "disclosed toxic genes encoding Bt proteins of about 67-68 kd." We do not consider this argument as it has been waived. Becton Dickinson & Co. v. C.R. Bard, Inc., 922 F.2d 792, 800 (Fed. Cir. 1990) ("[A]n issue not raised by an appellant in its opening brief . . . is waived.").

Even if we were to reach the issue, Bayer's argument ignores that the materiality of the Mariani notes is based not only on the size of the protein disclosed in her notes, but also on the notes' disclosure that Barnes had constructed a chimeric gene containing a 67 kD fragment of a Bt toxin gene fused to a kanamycin resistance gene attached to a plant promoter. Bayer overcame the Adang Gene reference by expressly arguing that it "fails to describe the development of a chimearic gene." It can, thus, not now argue that the Mariani notes, which do disclose a chimeric gene, are merely cumulative over the Adang Gene article. Moreover, unlike the Mariani notes, nothing in the Adang reference could refute Bayer's interpretation of the Barnes Abstract. A reference cannot be merely cumulative if there is no other reference which "refutes, or is inconsistent with" a position the applicant has taken in opposing an argument of unpatentability.

evidence of good faith, must indicate sufficient culpability to require a finding of intent to deceive." Digital Control Inc., 437 F.3d at 1319 (quoting Paragon Podiatry Lab., Inc. v. KLM Labs., Inc., 984 F.2d 1182, 1189 (Fed. Cir. 1993)). Direct evidence of intent to deceive is not necessary, but may be inferred from the surrounding circumstances. Critikon, Inc. v. Becton Dickinson Vascular Access, 120 F.3d 1253, 1256 (Fed. Cir. 1997). We have held that absent a credible reason for withholding the information, "[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." Id.; see also Bruno Indep. Living Aids, 394 F.3d at 1354 (holding that an "inference of deceptive intent may fairly be drawn in the absence" of a "credible explanation for the non-disclosure"); cf. Dayco Prods., 329 F.3d at 1367 ("Intent to deceive cannot be inferred simply from the decision to withhold the reference where the reasons given for the withholding are plausible.").

The district court did not clearly err in finding that Bayer's "attempts to establish subjective good faith sufficient to overcome the intent to mislead [were] not persuasive" and concluding that Meulemanns intentionally withheld the material Mariani notes with the intent to deceive the PTO. Monsanto II, slip op. at 97-98. Meulemanns himself admitted that he was aware of the notes during the prosecution of the '565 patent, that he had discussed the content of the notes with Mariani, and that the notes would have been important to the Examiner if the notes contained reliable information. The only explanation that Meulemanns or Bayer provided for failing to disclose the information contained in the notes was that the notes were not decipherable standing alone and that when Meulemanns discussed the notes with Mariani, Mariani had been unable to

remember "anything" about them. The district court, however, found this explanation to lack credibility, particularly in light of Mariani's ability to testify with clarity and detail about the contents of the notes during her deposition. We find nothing clearly erroneous in the court's credibility finding. See First Interstate Bank of Billings v. United States, 61 F.3d 876, 882 (Fed. Cir. 1995) ("[C]redibility determinations by the trial judge 'can virtually never be clear error.'" (quoting Anderson v. City of Bessemer, 470 U.S. 564, 575 (1985))); JVW Enters. v. Interact Accessories, Inc., 424 F.3d 1324, 1334 (Fed. Cir. 2005). And absent a credible reason for Meulemanns to have not understood the content of Mariani's notes after having discussed them with Mariani, the district court did not clearly err in inferring the requisite intent. See Bruno Indep. Living Aids, 394 F.3d at 1354. Intent is easily inferred when, as here, an applicant makes arguments to the PTO that it knows, or obviously should have known, are false in light of information not before the examiner, and the applicant knowingly withholds that additional information. See Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1368 (Fed. Cir. 2007) (holding that an applicant's argument that the information was withheld in "'good faith' does not negate an intent to manipulate the evidence" when "an applicant knows or obviously should know that information would be material to the examiner").

Having found without clear error that Bayer intentionally withheld material information when it failed to disclose the Mariani notes despite taking a position at the PTO that was refuted by the information contained in the notes, the district court had discretion to hold the '565 patent unenforceable for inequitable conduct. See Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1359 (Fed. Cir. 2003). As Bayer does

not challenge this discretionary decision, we affirm the district court's holding that the '565 patent is unenforceable for inequitable conduct.

Because the failure to disclose the information in the Mariani notes was alone sufficient to support holding the '565 patent unenforceable, we need not consider whether the statement Bayer made during the prosecution of the patent that its invention had solved the problem of unpredictability of expression of Bt toxins in plants also amounted to inequitable conduct.

III.

The district court also concluded that the '799, '372 and '546 patents were unenforceable for inequitable conduct. Bayer argues on appeal that the district court did not have jurisdiction to hold these three patents unenforceable. We review questions of jurisdiction de novo. See, e.g., Pennington Seed, Inc. v. Produce Exch. No. 299, 457 F.3d 1334, 1338 (Fed. Cir. 2006).

Although Monsanto initially sought a declaratory judgment that four Bayer patents were infringed, Bayer subsequently dismissed with prejudice its infringement claims under the '799, '372, and '546 patents and filed a Statement of Non-Liability, covenanting not to sue Monsanto for past, present, or future infringement of these patents. Even if filing such a covenant may divest the court of jurisdiction over a declaratory judgment action regarding these patents, see Amana Refrigeration, Inc. v. Quadlux, Inc., 172 F.3d 852, 855 (Fed. Cir. 1999); Fort James Corp. v. Solo Cup Corp., 412 F.3d 1340 (Fed. Cir. 2005), under our precedent the district court retained independent jurisdiction over Monsanto's request for attorney fees under 35 U.S.C. § 285. As this court recently explained:

> While the covenant [not to sue for infringement] may have eliminated the case or controversy pled in the patent-related counterclaims and deprived the district court of Article III jurisdiction with respect to those counterclaims, the covenant does not deprive the district court of jurisdiction to determine the disposition of . . . the request for attorney fees under 35 U.S.C. § 285.

Highway Equip. Co. v. FECO, Ltd., 469 F.3d 1027, 1033 n.1 (Fed. Cir. 2006) (internal citation omitted); see also H.R. Techs., Inc. v. Astechnologies, Inc., 275 F.3d 1378, 1385 (Fed. Cir. 2002).

The parties do not dispute that the district court's jurisdiction to rule on attorney fees encompassed the jurisdiction to make findings of inequitable conduct regarding all four patents. See Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp., 267 F.3d 1370, 1380 (Fed. Cir. 2001) ("A district court may award reasonable attorney fees to the prevailing party in a patent infringement case where the conduct of a party is deemed to be 'exceptional.' . . . . The prevailing party may prove the existence of an exceptional case by showing: inequitable conduct before the PTO . . . ." (quoting 35 U.S.C. § 285)).[17] The district court's holding that the '799, '372, and '546 patents are unenforceable stemmed directly from its inequitable conduct findings. See Monsanto II, slip op. at 95 ("The Court . . . finds by clear and convincing evidence that the equities warrant a conclusion that . . . Bayer committed inequitable conduct. . . . The '799 patent, the '372 patent, and the '546 patent are accordingly unenforceable."). The question facing this court is, thus, whether a district court's jurisdiction under § 285 to determine whether there was inequitable conduct in the prosecution of patents that are otherwise no longer in suit

[17] Inequitable conduct regarding the three withdrawn patents was relevant to the question of attorney's fees because Monsanto's request for attorney's fees included fees accumulated before the three patents had been withdrawn.

confers on that court the jurisdiction to hold such patents unenforceable for inequitable conduct. We hold that it does.

A district court has no discretion to decide whether a patent is unenforceable once it enters a finding of inequitable conduct. To the contrary, this court has long held that the unenforceability of a patent follows automatically once a patent is found to have been obtained via inequitable conduct. Kingsdown Medical Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 877 (Fed. Cir. 1988) (en banc in pertinent part) ("When a court has finally determined that inequitable conduct occurred in relation to one or more claims during prosecution of the patent application, the entire patent is rendered unenforceable." (emphasis added)); see also J.P. Stevens & Co. v. Lex Tex, Ltd., 747 F.2d 1553, 1560 (Fed. Cir. 1984) ("If the court reaches th[e] conclusion [that there was inequitable conduct], it must hold that the patent claims at issue are unenforceable."). Any distinction between the two findings is merely semantic. As a result, jurisdiction to decide whether a patent was obtained through inequitable conduct necessarily includes the jurisdiction to declare a patent unenforceable as a result of that inequitable conduct.

In an opinion issued after the briefs were filed in the instant case but prior to oral argument, this court explicitly held that a district court has the power to declare patents that are no longer in suit unenforceable for inequitable conduct. Nilssen v. Osram Sylvania, Inc., 504 F.3d 1223 (Fed. Cir. 2007). In Nilssen, the plaintiff had originally alleged that the defendant infringed fifteen patents related to electrical lighting products but withdrew four of the patents shortly before trial. The district court nevertheless held the four withdrawn patents unenforceable for inequitable conduct in the process of determining whether the patents which remained in the suit were unenforceable for

inequitable conduct. This court affirmed, explaining that "[b]ecause inequitable conduct with respect to one or more patents in a family can infect related applications, we find no abuse of discretion in the district court's holding the [four patents no longer in suit] unenforceable." Id. at 1230. In Nilssen the jurisdiction of the court to reach the inequitable conduct inquiry for the withdrawn patents was itself in question because the district court reached the issue only collaterally to determining whether there was inequitable conduct regarding patents that remained in suit. Here, the outcome is even clearer as there is no dispute that the court had an independent grant of jurisdiction under § 285 to consider inequitable conduct relating to the withdrawn patents. The district court, therefore, did not lack jurisdiction to hold the '799, '372, and '546 patents unenforceable.[18]

IV.

We affirm the district court's holding that the '565 patent is unenforceable for inequitable conduct, and we conclude that the court did have jurisdiction to declare the '799, '372, and '546 patents unenforceable. Since we affirm the court's holding that the '565 patent is unenforceable, we do not reach the remaining issues raised by Bayer on appeal. The final judgment of the district court is therefore

AFFIRMED.

Costs to appellee.

[18] Bayer does not, in this appeal, challenge the district court's findings of inequitable conduct regarding the '799, '372, and '546 patents. Therefore, those findings are affirmed. We do not address the impact of those findings on the question of attorney fees under section 285.