UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS

PROMEGA CORPORATION, *Plaintiff*,	)	No. 13 C 2333
v.	)	Judge Richard A. Posner
APPLIED BIOSYSTEMS, LLC, LIFE TECHOLOGIES CORPORATION, and CALIFORNIA INSTITUTE OF TECHNOLOGY, *Defendants.*	)	

ORDER OF APRIL 4, 2013

On March 28, 2012, I conducted a hearing on claims construction for U.S. Reissued Patent No. RE43,096, and Promega and the defendants' (whom I'll refer to collectively as Life Tech) motions for summary judgment on infringement, reissue recapture, patent prosecution laches, and breach of a 2006 cross-licensing agreement between the parties. On the basis of that hearing and the parties' briefs, I adopt the following claim constructions, see *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978–79 (Fed. Cir. 1995) (en banc), affirmed, 517 U.S. 370 (1996), and resolve each summary judgment motion.

Claim Construction

"A method of nucleic acid sequencing analysis." The first claim construction dispute concerns the preamble to claim 62 of the patent, which describes "a method of nucleic acid sequencing analysis." The parties dispute whether this language is meant to limit the scope of the invention in the body of the claim, which defines the method's steps. They also dispute the meaning of the phrase.

"In general, the purpose of a claim preamble is to give context for what is being described in the body of the claim," rather than to limit the scope of the claimed invention, *Symantec Corp. v. Computer Associates Int'l, Inc.*, 522 F.3d 1279, 1288 (Fed. Cir. 2008). But the preamble may be limiting "if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim." *Id*. And that is the case here. Without the preamble, claim 62 merely describes a method of extending a DNA strand that has been fluorescently tagged. The process is meaningful only because it allows a

biochemist to obtain information about the DNA strand—indeed, that is what the inventors said distinguishes the invention from prior art that succeeded in fluorescently tagging a DNA strand, but that could not be used in DNA sequencing operations. I therefore construe the preamble to claim 62 as limiting.

Although the preamble is limiting, nothing in the patent limits its meaning, as Promega suggests, to "determining the identity and order of nucleotides in a DNA molecule at a single nucleotide resolution"—that is, determining each and every nucleotide in the strand (for example, ATTCGTACGAT). If the inventors wanted to so limit their claim, they could have claimed a "method of DNA sequencing," as they did repeatedly in earlier patent applications, and indeed in the preamble to claim 64 of the current patent. Instead, in drafting claim 62, they chose the broader term "nucleic acid sequence analysis," which encompasses any type of analysis of a genetic sequence, even if not at a single nucleotide resolution. Such analysis might reveal, for example, the number of times the strand repeats a particular pattern of nucleotides (e.g. GATAGATAGATA) or the existence of a mutation in the sequence. Life Tech lists several other examples: "fragment analysis, short tandem repeat analysis, restriction fragment length polymorphism, Southern hybridization, chain termination sequencing, and microsatellite loci analysis." At least as early as 1992, the inventors made it clear to the patent examiner that the "claimed invention is not limited to the use of fluorescent compounds to actually sequence nucleic acids," as the examiner stated in a July 2, 1992 action on the patent application.

Therefore, I construe the preamble "a method of nucleic acid sequence analysis" to limit Life Tech's claims to "any method of obtaining information about a genetic sequence."

"Oligonucleotide." Life Tech suggests that the remaining disputed terms should be given their "plain and ordinary meanings," but that phrase is a misnomer in this context. How can a technical term such as "oligonucleotide" have a plain meaning to a layperson? What Life Tech really means is that each term has a widely accepted meaning among biochemists, which is used in the patents. Promega responds that the patent adopts a narrower, idiosyncratic meaning for each term, limited to sequencing reactions. It correctly points out that the inventor is free to act as his own lexicographer by providing a definition in the specification that is narrower than a term's usual usage. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313–14 (Fed. Cir. 2005) (en banc). But in each case Promega's evidence that the inventors have done this is very weak.

Life Tech proposes that "oligonucleotide" be construed as "a short polymer, in general a chain of under 200 bases, consisting of a linear sequence of four nucleotides in a defined order." This construction is based on a description of "oligonucleotide" added to the specification of the '096 patent on reissue, see col. 3, ll. 6–7, and Life Tech cites in further support two patent applications cited in the '096, which explain that strands

under 200 bases are generally termed "oligonucleotides," while longer chains are called "polynucleotides." U.S. Patent No. 4,948,882, col. 2, ll. 32–34; U.S. Patent No. 5,541,313, col. 2, ll. 32–34.

Promega does not contest that the defendants' definition is accepted among biochemists. Instead it argues that the patent uses its own definition of "oligonucleotide." It first points to the specification's statement that "primers" must have four narrow characteristics: "1) They must have a free 3′ hydroxyl group to allow chain extension by the polymerase. 2) They must be complementary to a unique region 3′ of the cloned insert. 3) They must be sufficiently long to hybridize (that is, attach to an existing single strand of DNA) to form a unique, stable duplex. 4) The chromophore or fluorophore must not interfere with the hybridization or prevent 3′-end extension by the polymerase." (col. 5, l. 66–col. 6, l. 6.) The mention of a "cloned insert" (a DNA strand with a known sequence attached to an unknown strand to facilitate replication) suggests that the primers are useful only in sequencing reactions (which involve replicating an unknown strand). In the 2001 litigation over the '748 patent, as I'll explain in more detail later on, the district court adopted this construction and thereby limited the term "primer" to the subset of primers used in DNA sequencing applications. *Promega Corp. v. Applera Corp.*, 2002 WL 32355680 at *10–13 (W.D. Wis. 2002).

Promega argues that the specification requires "oligonucleotide" to have the same construction as "primer." It notes the patent's statement that "the primer is either a synthetic oligonucleotide or a restriction fragment" (col. 2, ll. 5–6), but this does not logically imply that all oligonucleotides are primers, as Promega suggests. (All cats are either female or male, but not all females are cats.) The specification also uses the word "oligonucleotide" (or "oligonucleotide primers") to refer to the primers in sequencing reactions; but this again does not mean that the word always refers to primers. As a counterexample, the specification's Example IV describes the process of attaching the fluorescent tags to DNA strands which may or may not be sequencing primers. (Col. 9, l. 28–col. 10, l. 50.) The example consistently uses the term "oligonucleotide" instead of "primer," further indicating that the two are not interchangeable.

Promega also claims that a narrow definition of "oligonucleotide" is required because of statements the inventors made during prosecution of the '748 to distinguish various pieces of prior art. The inventors said that the claimed oligonucleotides are shorter than the "polynucleotides" claimed in one reference (Draper); to distinguish other references, they added that the oligonucleotides claimed in the patents are extendable and capable of hybridizing to a specific sequence. These statements are either consistent with the usual meaning of "oligonucleotide" or relate to other terms in the asserted claims. Promega has not shown that the inventors departed from the term's usual meaning, and I therefore adopt Life Tech's proposed construction.

"Four sets of oligonucleotides." Promega suggests that this term be defined as "four sets of oligonucleotides capable of generating size-nested sets of DNA fragments that contain, in their collection of lengths, the information necessary to define a sequence of oligonucleotides." The phrase "four sets" is a common English phrase that is not used counterintuitively in the '096 patent. Having already construed "oligonucleotide," I agree with the defendants that this term does not require construction.

"Complementary strand of DNA." In biochemistry, the word "complementary" refers to base-pairing rules. In a double strand of DNA, each nucleic acid base in one strand pairs with only one base in the other strand—adenine (A) with thymine (T), and cytosine (C) with guanine (G). Life Tech therefore proposes that the term be construed as "a strand of DNA with corresponding molecules."

Promega does not dispute that this is the accepted meaning of the phrase, but it argues that the phrase as used in the '096 patent means "a cloning vector"—which, as I said earlier, is a known DNA sequence attached to an unknown sequence to facilitate replication. It's true that the specification sometimes uses the phrase "complementary strand of DNA" to refer to a cloning vector, but only when it is already clear that the strand is a cloning vector. This does not establish that the phrase always refers to cloning vectors. And the patent also describes a "complementary stretch of DNA" used in fluorescent labeling (that is, prior to sequencing), and this strand is not a cloning vector (col. 6, ll. 65–66). I adopt Life Tech's proposed construction.

"Duplex." The defendants' proposed construction is "a double-stranded part of a nucleic acid molecule," a generally accepted biochemical definition. Promega responds only that the definition of duplex is "inextricably linked" to its other proposed constructions limiting the claim terms to sequencing reactions, which I have already rejected. I adopt Life Tech's proposed construction.

"Polymerase." Life Tech proposes to construe the term as "an enzyme capable of catalyzing the formation of a polymer from monomers." (A "polymer" is a molecule which consists of linked repeating units; these units are smaller molecules called "monomers.") Promega's proposed construction is "polymerase used to perform sequencing reactions, such as the Klenow fragment of DNA polymerase."

Once again Promega attempts to artificially limit a term's construction to DNA sequencing reactions—in this case by adding words to the construed term itself. While Promega is correct that the specification mentions polymerase only in the context of sequencing, that alone does not indicate that the inventors limited the term's meaning to sequencing and thereby deviated from the accepted scientific meaning. Life Tech's construction is adopted.

"Fluorophore." Life Tech construes the term to mean "a fluorescent molecule or molecular component." Promega does not contest that this is the accepted biochemical definition, but it proposes the definition "fluorescent tag that may be coupled to an oligonucleotide to establish a correlation with a distinct nucleotide and to allow for the identification of said molecule." Promega's construction describes the function of the fluorophore in the sequencing process, but nothing in the specification limits the term itself to that process. Fluorophores are useful in reactions other than sequencing, and neither the specification nor the prosecution history indicates that the inventor meant that term to narrow the term "fluorophore" to a tag used in sequencing, which is the import of Promega's proposal. I adopt the defendants' proposed construction.

"specifically hybridized to the complementary strand of DNA." Although neither party has formally requested a construction of the phrase "specifically hybridized" or proposed a concrete definition, Promega's opposition to Life Tech's infringement allegations requires a very specific construction of the term. The asserted '096 claims describe an oligonucleotide "specifically hybridized" to a complementary DNA strand—that is, engineered to bind to a locus having a complementary nucleotide sequence. Promega contends that the oligonucleotides it provides as part of its DNA fingerprinting systems aren't "specifically hybridized" to their intended locus because they can potentially bind to more than one locus of the genomic DNA being tested. This argument is premised on a construction of "specifically hybridized" that covers only hybridization to a unique locus, and is therefore a belated request for additional "rolling" claim construction, e.g. *Pfizer, Inc. v. Teva Pharmaceuticals, USA, Inc.*, 429 F.3d 1364, 1377 (Fed. Cir. 2005). I must construe the claim term before evaluating infringement. Cf. *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008).

Promega's proposed interpretation is unreasonably narrow. The asserted '096 claims describe oligonucleotides that are useful because they bind to a specific locus; the claims say nothing about whether that locus must be unique. For certain nucleic acid sequence analysis applications—DNA fingerprinting, for example—it's clear that the locus needn't be unique because chains extended from erroneously-bound oligonucleotides are easily disregarded. Other applications like DNA sequencing do rely on the oligonucleotide's binding to a unique locus, but the patent isn't limited to DNA sequencing, as I explained above. Promega hasn't explained why the '096 inventor would have sought to cover only this latter subclass of applications, thus excluding applications involving oligonucleotides hybridized to non-unique loci from the scope of its patent. More likely the inventor intended oligonucleotides "specifically hybridized to the complementary strand of DNA" to refer to the entire class of oligonucleotides targeted at a specific DNA locus. I construe the phrase to mean "hybridized to a specific locus on a complementary strand of DNA, even if that locus is not unique."

Infringement

Life Tech has moved for summary judgment of infringement as to Promega's products in the field of DNA fingerprinting, a method of analyzing two DNA samples to determine whether they came from the same person. Promega's products work by comparing the length of short tandem repeat sections of each sample. A short tandem repeat (or STR) locus is a DNA region where the same nucleotide sequence is repeated multiple times (e.g. CTACTACTACTA), with the number of repetitions varying from person to person. If two samples' corresponding STR regions are the same length, it means they repeat the same number of times, and it's more likely that they came from the same person. But any given STR locus isn't so variable that a single match is conclusive, so multiple STR loci must be measured and compared. Each match increases the confidence of a valid identification.

For the purpose of these motions, Life Tech asserts that Promega's PowerPlex 16 HS System is representative of its DNA fingerprinting products. See "PowerPlex 16 HS System," www.promega.com/products/genetic-identity/str-analysis-for-forensic-and-paternity-testing/powerplex-16-hs-system/ (visited March 31, 2013). I will consider that product when evaluating Life Tech's motions for summary judgment of infringement. Promega formally disputes that it stipulated that the PowerPlex 16 HS System is representative of Promega's STR-analysis products, but it has provided no explanation of how its other products may differ. If the following opinions about Promega's infringement of the '096 patent do not apply to Promega products other than the PowerPlex 16 HS System, Promega may move to limit the scope of this order. Any such motion must clearly address how the additional products differ from the PowerPlex 16 HS System, and why such differences are relevant to infringement of the asserted claim terms.

The PowerPlex 16 HS System performs DNA fingerprinting by comparing sixteen different STR loci between the two samples. In order to measure the length of each STR locus, it must be "amplified" by creating multiple copies. Amplification involves fluorescently-tagged oligonucleotides that are complementary to the nucleotide sequence immediately preceding each STR region. The tagged oligonucleotide binds to the target locus of the sample and is extended using a polymerase to complete a complementary copy of the STR region. The PowerPlex technical manual contains instructions for amplifying and measuring the STR copies, and Promega provides the necessary polymerases and tagged oligonucleotides to perform the process.

Life Tech is entitled to summary judgment of infringement if it presents undisputed evidence that each claim limitation is present in Promega's product, such that no reasonable jury could find otherwise. *Innovention Toys, LLC v. MGA*

Entertainment, Inc., 637 F.3d 1314, 1319 (Fed. Cir. 2011). Life Tech alleges that Promega's products infringe claim 62 of the '096 patent and two of its dependent claims. Claim 62 reads:

> 62. A method of nucleic acid sequence analysis, comprising extending an oligonucleotide along a complementary strand of DNA of a duplex by a polymerase to produce a labeled extension product, wherein the duplex comprises the oligonucleotide specifically hybridized to the complementary strand of DNA, and wherein the oligonucleotide is covalently coupled to a fluorophore so as to allow chain extension by the polymerase.

The preamble, "a method of nucleic acid sequence analysis," is a claim limitation, and it means "a method of obtaining information about a genetic sequence." Promega's product measures and compares the length of specific STR sections. Promega doesn't dispute that the length of an STR strand is information about a genetic sequence, so I determine that its products practice the limitation articulated by the preamble.

The claim is next limited to the process of "extending an oligonucleotide along a complementary strand of DNA of a duplex by a polymerase to produce a labeled extension product." As I explained above, this is exactly what takes place when a DNA sample is amplified as part of the PowerPlex 16 HS System. Each tagged oligonucleotide supplied by Promega binds to a complementary section of the sample strand to form a duplex and is then extended by a polymerase. The product is "labeled" by the fluorescent tag attached to the oligonucleotide. The excerpts from the PowerPlex 16 HS System Technical Manual provided by Life Tech confirm this description. Promega's expert opinions to the contrary are based on Promega's rejected claim constructions, and therefore don't create a triable factual dispute.

Claim 62 is further limited to processes "wherein the duplex comprises the oligonucleotide specifically hybridized to the complementary strand of DNA." Promega concedes that it provides nucleotides engineered to hybridize to specific locations in a DNA sample, but disputes that these oligonucleotides are *specifically* hybridized because each can potentially bind to multiple loci on human genomic DNA. Having rejected the claim construction on which this argument is premised, I conclude that the PowerPlex 16 HS System practices this limitation.

Finally the claim requires that "the oligonucleotide is covalently coupled to a fluorophore so as to allow chain extension by the polymerase." Promega agrees that Figure 23 of the PowerPlex 16 HS System Technical Manual "evinces fluorescently labeled amplification products." It is undisputed (given my claim constructions) that the amplification products contain oligonucleotides labeled by being coupled to a fluorophore by means of a linker molecule. Promega counters by citing its expert's rebuttal report but to no avail; the expert's discussion is specific to the term "fluorescent nucleotides," which appears only in claim 70 (discussed *infra*). If anything, the expert's

discussion of linker molecules confirms that the fluorophore is covalently bonded to the oligonucleotide.

Life Tech has produced evidence indicating that the PowerPlex 16 HS System practices every limitation in '096 claim 62. The only factual disputes Promega raises in opposition rely on its proposed claim constructions, which I have uniformly rejected. Therefore I GRANT partial summary judgment that Promega's PowerPlex 16 HS System literally infringes claim 62, without taking any position on the validity of the claim. *Pandrol USA, LP v. Airboss Ry. Products, Inc.*, 320 F.3d 1354, 1365 (Fed. Cir. 2003).

Life Tech also alleges that the Promega's products infringe claim 63, which is dependent on claim 62. It reads:

> 63. The method of claim 62, further comprising separating said labeled extension product from said duplex

Life Tech, citing the PowerPlex 16 HS System Technical Manual explains that a step in the application protocol requires denaturing the amplified STR duplexes—heating the mixture until the nucleotide bonds between the tagged strands (the "labeled extension product") separate from the sample DNA. This constitutes "separating said labeled extension," as described in claim 63. Promega disputes the construction of "duplex," but doesn't quibble with Life Tech's characterization of the denaturation process. Partial summary judgment of literal infringement of claim 63 is therefore GRANTED, without taking any position on the validity of the claim. *Id*.

Life Tech also alleges that Promega's products infringe claim 70, which is also dependent on claim 62. It reads:

> 70. The method of claim 62, wherein substantially all molecules of the labeled extension product individually comprise a single fluorescent nucleotide.

As I stated earlier, Promega tags each oligonucleotide by attaching a fluorophore to a constituent nucleotide by means of a linker molecule. Promega argues that this doesn't count as a "fluorescent nucleotide" because the linker molecule separates the fluorophore from the nucleotide, and the oligonucleotide is often synthesized before the fluorophore-linker component is coupled to its 5′ terminal nucleotide. But all the "fluorescent nucleotides" disclosed by the patent involve coupling fluorophores to nucleotides—Promega identifies no other method of making a nucleotide fluorescent. And Promega's expert mentions no reason why the order in which the components are combined has any scientific effect on the end result. Promega has not asked me to construe the term "fluorescent nucleotide," and has proposed no intelligible definition

of the term that would exclude its product based on the separation between the nucleotide and the fluorophore-linker structure. So a fluorophore coupled to the terminal nucleotide constitutes a "fluorescent nucleotide."

Promega also challenges Life Tech's evidence that its products infringe. Claim 70 covers extension products—in this case the STR strands created during amplification—which "individually comprise a single fluorescent nucleotide." The use of the open-ended transitional phrase "comprising" signals that each STR strand must contain a single fluorescent nucleotide, though it contains additional components as well. *MagSil Corp. v. Hitachi Global Storage Technologies, Inc.*, 687 F.3d 1377, 1383–84 (Fed. Cir. 2012). The limitation excludes STR strands containing multiple fluorescent nucleotides, either as part of the initial oligonucleotide or added during chain extension. If STR strands with multiple fluorescent nucleotides were covered by claim 70, that claim would be indistinguishable from claim 62, and would violate the doctrine of claim differentiation that "two claims of a patent are presumptively of different scope." *Kraft Foods, Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1366 (Fed. Cir. 2000). Promega's expert has opined that certain Promega products label oligonucleotides use energy transfer dyes involving multiple fluorophores. Life Tech has not addressed which products employ multi-fluorophore labels, or whether any amplified STR chains contain multiple fluorescent nucleotides. Because of the remaining uncertainty as to the specific manner in which Promega's amplified STR chains are fluorescently labeled, I DENY Life Tech's motion for summary judgment of literal infringement of claim 70.

Finally, Life Tech has moved for partial summary judgment that Promega's representative product infringes claim 66 of the '096 patent. Claim 66 is independent of claim 62, and describes a composition created during the synthesis of DNA rather than a process for performing that synthesis. Claim 66 reads:

> 66. A mixture comprising a *polymerase* and a *duplex*, wherein the duplex comprises an *oligonucleotide specifically hybridized* to a *complementary strand of DNA*, wherein the *oligonucleotide* is covalently coupled to a *fluorophore* so as to allow chain extension by the polymerase.

The parties disputed the construction of the italicized terms, and I have rejected Promega's specialized definitions in favor of Life Tech's broader definitions that comport with the commonly-understood meanings of each term in the industry.

Promega argues that there's no evidence establishing that the PowerPlex 16 HS System embodies every limitation of claim 66. But Life Tech's citations to the PowerPlex 16 HS System Technical Manual are sufficient. Promega provides, as part of the PowerPlex 16 HS System, the polymerase and tagged oligonucleotides. Given my claim construction, there's no dispute that the latter are "covalently coupled to fluorophores."

Following Promega's protocol, the tagged oligonucleotides will bind to specific loci on the DNA strand that is to be analyzed and the polymerase will extend the bound oligonucleotide to create a copy of desired STR region. Repetition of the process will result in multiple amplified STR strands, each of which is a duplex. Life Tech's proffered evidence supports a finding that the mixture created after the polymerase chain extension has completed but before the amplified duplexes are denatured embodies the composition of claim 66, and Promega's arguments to the contrary all depend on claim constructions which I have rejected. I therefore GRANT partial summary judgment that the PowerPlex 16 HS System literally infringes claim 66 of the '096 patent.

Reissue recapture

The parties also seek summary judgment as to whether the '096 patent is invalid under the doctrine of reissue recapture. Reissue allows an inventor to amend a patent that has already been granted to correct an error in drafting, including "an attorney's failure to appreciate the full scope of the invention." *Medtronic, Inc. v. Guidant Corp.*, 465 F.3d 1360, 1375 (Fed. Cir. 2006). An inventor may use the process to broaden the claims in the patent if, "through error without any deceptive intention," he "claim[ed] … less than he had a right to claim in the patent." 35 U.S.C. § 251(a). A broadening reissue is only permitted "within two years from the grant of the original patent." 35 U.S.C. § 251(d), and does not extend the patent term—the reissued patent is valid only for "the unexpired part of the term of the original patent." 35 U.S.C. § 251(a).

The doctrine of reissue recapture "bars a patentee from recapturing subject matter, through reissue, that the patentee intentionally surrendered during the original prosecution in order to overcome prior art and obtain a valid patent," *In re Youman*, 679 F.3d 1335, 1343 (Fed. Cir. 2012), because in such circumstances the failure to claim the surrendered subject matter "cannot be said to involve the inadvertence or mistake contemplated by 35 U.S.C. § 251." *MBO Laboratories, Inc. v. Becton, Dickinson & Co.*, 602 F.3d 1306, 1313 (Fed. Cir. 2010). An inventor surrenders subject matter if, during patent prosecution, he "clearly and unmistakably argue[s] that his invention does not cover certain subject matter to overcome an examiner's rejection based on prior art." *Id.* at 1314. The question on summary judgment is whether the inventors clearly and unmistakably argued that their invention does not cover methods of nucleic acid sequence analysis other than DNA sequencing. Answering that question requires me to review the patent prosecution history.

In 1984, the inventors made a breakthrough in biochemistry by developing a way to attach a fluorescent tag to a DNA strand without preventing that strand from extending during replication. At the time, the sole known use of the method was in DNA sequencing, so the inventors drafted patent claims specific to DNA sequencing—for example, claims 1–12 of the original patent application (Application No. 06/570,973),

which claimed improvements to the chain degradation and chain termination sequencing methods. But before the patent issued, other uses of the method were developed. An inventor "is entitled to the benefit of all the uses to which [his invention] can be put, no matter whether he had conceived the idea of the use or not," *Roberts v. Ryer*, 91 U.S. 150, 157 (1875), and so the inventors amended their claims to include uses related to other types of nucleic acid sequence analysis. By at least 1992, as I noted earlier, it was clear to the examiner that the claimed invention was not limited to DNA sequencing.

When the original patent (U.S. Patent No. 6,200,748) was finally granted in 2001, many of the allowed claims made no mention of DNA sequencing. Life Tech's predecessor to the patent rights, Applera, sued Promega for infringement. See *Promega Corp. v. Applera Corp.*, 01-C-244-C, 2002 WL 32355680 (W.D. Wis. Jan. 2, 2002). During claim construction, Applera argued that two terms in the patent claims—"primer" and "template"—should be given their ordinary scientific meanings, while Promega argued, as it has here, for narrower constructions that would effectively limit the patent's reach to DNA sequencing. Judge Crabb sided with Promega, holding that the inventors "chose to be their own lexicographers" by including specific definitions of the terms "primer" and "template" in the patent specifications. *Id.* at *10, *14. The parties settled (perhaps to avoid a final judgment that would give that claim construction preclusive effect, e.g., *Talmage v. Harris*, 486 F.3d 968, 974 (7th Cir. 2007)), agreeing to cross-license patents that each side had asserted in the litigation, and in 2003 the inventors filed a reissue application to amend their claims.

The inventors' inadvertent error in the '748 patent was to use the terms "primer" and "template"—terms that they had defined narrowly in the specifications. Had they anticipated Judge Crabb's narrow construction during prosecution of the '748 patent, they would have known that they were claiming less than they were entitled to claim, and would have been entitled to amend the claims to use more general terms such as "oligonucleotide" and "complementary strand," as they later did in the reissued patent. Since this error did not become apparent until after the '748 was issued and was subsequently construed, they were entitled to fix it through the reissue process.

Promega argues that, by tying the scope of their invention to DNA sequencing in order to overcome prior art cited by the patent examiner during prosecution, the inventors surrendered all other methods of nucleic acid sequence analysis. But none of the prior art cited during prosecution involved nucleic acid sequence analysis. The examiner instead questioned whether the invention was obvious in light of four pieces of prior art: the chain degradation and chain termination methods of DNA sequencing; the "Kaplan" patent (U.S. Patent No. 4,151,065), which taught separating DNA strands by length using a process called "electrophoresis" and detecting the separated material using ultraviolet light; and the "Khanna" patent (U.S. Patent No. 4,318,846), which taught fluorescently tagging a DNA strand. None of these references made it possible to

extend a fluorescently tagged DNA strand and thus enable the use of fluorescent tagging in any method of nucleic acid sequence analysis, including DNA sequencing. The inventors made this clear during prosecution, stating for example that none of the cited prior art was "at all pertinent to the present invention and suggest nothing at all in relation to DNA sequencing." There is no clear statement in the record that the inventors intended to surrender methods of nucleic acid sequence analysis other than DNA sequencing. Even if their statements could be misunderstood to limit their claims to DNA sequencing, they quickly corrected this misapprehension, long before the '748 patent issued, and thus renounced any benefit from narrowing the scope of their invention.

Life Tech's motion to grant summary judgment that Promega has failed to meet its burden as to the doctrine of reissue recapture is therefore GRANTED, and Promega's contrary motion is DENIED.

Patent Prosecution Laches

Promega seeks summary judgment that laches bars Life Tech's claim of infringement because the patent's inventors were responsible for an "unreasonable and unexplained delay in prosecution," to Promega's prejudice. *Symbol Technologies, Inc. v. Lemelson Medical, Education & Research Foundation*, 422 F.3d 1378, 1384–86 (Fed. Cir. 2005). The patent prosecution history in this case is long–the original '748 patent issued in 2001, seventeen years after the initial 1984 application and during that seventeen-year period the inventors requested, and were granted, numerous extensions of PTO filing deadlines. However, Promega has not shown that the inventors deliberately delayed prosecution, either to enable Life Tech to capture later-developed technology or to extend the term of the patent. Nor has Promega shown that any of the delays were unreasonable.

Promega argues that the inventors unreasonably delayed issuance by abandoning Continuation Application Nos. 07/660,160 (Feb. 21, 1991) and 07/898,019 (June 21, 1992) even though each of those applications include claims that had been allowed by the patent examiner. "Refiling an application solely containing previously-allowed claims" "can be considered an abuse of the patent system," (the key word is "solely") but only if the refiling was "for the business purpose of delaying" the patent. *Symbol Technologies, Inc. v. Lemelson Medical, Education & Research Foundation*, *supra*, 422 F.3d at 1385. The '160 and '019 applications were continued in order to pursue claims that had been rejected and to add new claims; there is no showing that the continuations were filed for delay. And these two continuations account for just a handful of the many years of the prosecution history—hardly the "egregious case of misuse of the statutory patent system" required for prosecution laches. *Id.* at 1385.

Nor has Promega proved prejudice; it cannot explain what it would have done differently if the patent had issued earlier, or how it relied on, or was harmed by, the

delay. Promega raises the specter that long patent prosecutions will hide inventions from the public, slowing scientific progress. But that did not occur here; subject to some exceptions, patent applications are published 18 months after filing, see 37 C.F.R. § 1.211, and in this case, the invention was described, at least in part, in published scholarship as early as 1986. See Erich Strauss, et al., "Specific-Primer-Directed DNA Sequencing," 154 *Analytical Biochemistry* 353 (1986). No one disputes that the invention gained widespread use in the genetic analysis industry despite the delay. Promega's motion for summary judgment as to the defense of laches is therefore DENIED.

Priority Date

Life Tech has moved for summary judgment that the '096 patent has a priority date of January 16, 1984, which Promega challenges under the requirements of co-pendency and enablement. A patent can claim the priority date of an earlier patent application only if (1) the earlier application disclosed the same invention; (2) at least one inventor is common to both applications; (3) the later application specifically refers to the prior application, and (4) the current application was filed before the prior application was patented or abandoned. 35 U.S.C. § 120 (1988). The PTO approved the '096 patent as a continuation of a series of patent applications dating back to the original '973 application, filed January 16, 1984. The date of the patent is presumed correct, unless Promega can prove otherwise. *Technology Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1330–31 (Fed. Cir. 2008).

Promega alleges that there was a break in the co-pendency of the chain of applications when one of the applications from which Life Tech claims priority, Application No. 07/106,232, was abandoned on February 20, 1991, one day before the next application in the chain (the '160 application, filed February 21). If so, the two applications were not pending at the same time, and the '096 patent cannot claim priority prior to February 21, 1991. But the argument is waived because it was not presented in Promega's Invalidity and Unenforceability Contentions, which raise specific challenges to the priority date but say nothing about 1991 or the co-pendency rule; and Promega has not moved to update those contentions. See, e.g. *McDavid Knee Guard, Inc. v. Nike USA, Inc.*, 809 F. Supp. 2d 863, 878 (N.D. Ill. 2011).

Even if the issue was not waived, Promega's argument fails because there is no gap in co-pendency. The '232 application was abandoned when the inventors failed to file an appellate brief within two months of their notice of appeal. 37 C.F.R. §§ 1.192, 1.197 (1991); Manual of Patent Examining Procedures (MPEP), § 1215.04 (5th ed., revision 13, 1989) (the manual in effect at the time of the alleged break in co-pendency), www.uspto.gov/web/offices/pac/mpep/old/index.htm. The parties agree that under 37 C.F.R. § 1.8 the brief deadline runs from the date when the PTO *receives* an effective notice of appeal. The inventors' notice of appeal was due September 19, 1990, but was filed late, and so did not become effective until December 24, 1990, when the PTO

received a Request for an Extension of Time, MPEP, *supra*, § 1205, triggering a deadline of February 25, 1991 to file an appellate brief. The '160 continuation patent was timely filed four days before that deadline lapsed and rendered the '232 patent abandoned.

Moreover, the gap was at most a single day and could not have prejudiced anyone. The fate of protection for intellectual property protection for a major DNA invention should not be allowed to turn on a slip of scheduling of a single day, over twenty years ago. Cf. *Aristocrat Technologies Australia PTY Ltd. v. Int'l Game Technology*, 543 F.3d 657, 663 (Fed. Cir. 2008). These arguments have been made to the PTO, yet it still issued the patent and credits the 1984 priority date. I do not disagree.

Because I find for Life Tech on waiver and date of abandonment, I do not reach Life Tech's other arguments that may cure the alleged gap in co-pendency, such as whether there were still claims pending after February 25, 1991 from the '232 application and whether priority can be traced through the application 07/558,312.

Promega also argues that Life Tech cannot claim priority based on its earliest applications because those applications did not enable a person of ordinary skill in the art to practice the invention. A patent can only claim priority from an earlier application if the earlier application disclosed the claimed invention in accordance with 35 U.S.C. § 112. 35 U.S.C. § 120 (1988). The '096 patent specification discloses that the invention can be practiced by fluorescently tagging primers that meet four specific criteria,: "1) They must have a free 3' hydroxyl group to allow chain extension by the polymerase. 2) They must be complementary to a unique region 3' of the cloned insert. 3) They must be sufficiently long to hybridize to form a unique, stable duplex. 4) The chromophore or fluorophore must not interfere with the hybridization or prevent 3'-end extension by the polymerase." It teaches that "one such primer is the 15-mer 5' CCC AG TCA CGA CGTT 3'." Patent No. RE43,096, Col. 5–6. Earlier patent applications disclosed merely the use of a 12-mer primer, or a 15-mer primer without mentioning the conditions. Application Nos. 06/570,973 (Jan. 16, 1983); 06/689,013 (Jan. 2, 1985); 06/722,742 (Apr. 11, 1985).

Promega alleges that neither the 12-mer primer disclosed in the '973 application, nor a 15-mer that doesn't meet the four criteria for a primer, can be used in DNA sequencing, and thus that the application would not enable a biochemist to practice the invention in a useful way without undue experimentation. Promega points to some of the inventor's contemporaneous notes that suggest that 12-mer primers produced unsatisfactory results; a contemporaneous article from another inventor, which concludes that there were problems with the DNA tests using the 12-mer primer, Erich Strauss, et al., "Specific-Primer-Directed DNA Sequencing," 154 *Analytical Biochemistry* 353 (1986); and at least one expert who concludes that the early applications did not enable the invention, in part because there were problems with the 12-mer primer.

Life Tech responds only that by 1984 scientists were doing DNA analysis with 12-mer primers, admittedly with radioactive rather than fluorescent tags, and that the

lab notes are inconclusive. Promega has therefore raised a question of material fact as to which patent application first enabled the invention. Life Tech's motion for summary judgment as to the priority date of the '096 patent is DENIED.

Breach of the 2006 Cross-License Agreement

Promega and Life Tech's predecessor agreed in 2006 to cross-license each others' patents so that both could sell products that perform genetic identity analysis, such as paternity testing and forensic DNA identification. Life Tech has demanded royalties from Promega for its use of the '096 patent and contends that Promega breached the 2006 cross-license agreement by refusing to pay.

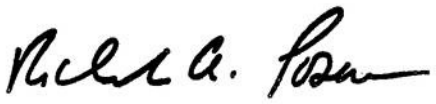
The agreement obliges Promega to pay Life Tech 2% of its net sales of all "Licensed Products" from the date that Life Tech obtained a reissue of its '748 patent, which occurred on Jan. 10, 2012 when the '096 patent was granted. Life Tech's claim thus turns on which, if any, of Promega's products are "Licensed Products," defined in the agreement as "any product ... the manufacture, import, use, offer for sale or sale of which, but for the license granted in ... this Agreement would ... infringe at least one Valid Claim of any [Life Tech] patent." This definition, combined with the agreement's emphatic disclaimer that "NOTHING CONTAINED IN THIS AGREEMENT WILL BE CONSTRUED AS … AN ADMISSION BY EITHER PARTY THAT ANY OF ITS PRODUCTS INFRINGE ANY PATENTS OF THE OTHER PARTY" (capitalization in original), effectively requires an outside determination of which products infringe. I have made that determination by granting Life Tech's motions for summary judgment of infringement of claims 62, 63, and 66.

Promega argues that Life Tech's contract claim must be postponed until after all validity challenges to the '096 are adjudicated, on the theory that an invalid patent cannot be infringed and the scope of Promega's "Licensed Products" still cannot be determined until the patent's validity is established. That may be true as a matter of patent law (but see *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 1583 (Fed. Cir. 1983) ("though an invalid claim cannot give rise to liability for infringement, whether it is infringed is an entirely separate question capable of determination without regard to its invalidity")), but this is a contract dispute. The agreement defines "Valid Claim" as "a claim of an issued patent that ... has not been held permanently invalid or otherwise unenforceable by a court of competent jurisdiction in a final and unappealable or unappealed ... judgment." Claims 62, 63, and 66 of the '096 patent meet this definition of "Valid Claim."

Finally, Promega notes that the cross-license agreement provides each side with a 30-day period within which to cure any material breaches, and the period is tolled during the pendency of litigation. But the cure period and tolling provision limit only a party's right to terminate the agreement; Life Tech is seeking to enforce it, not terminate

it. The provisions do not toll the parties' contractual obligations, and they do not suspend any determination of breach or damages, as Promega contends.

Promega's DNA fingerprinting products infringe claims 62, 63, and 66 of the '096 patent. All of the claims are "Valid" as defined in the cross-license agreement. Promega, therefore, is obliged to pay 2% of their net sales revenue as royalties, and its failure to do so constitutes breach. Life Tech's motion for summary judgment that it has breached the cross-license agreement is GRANTED.



United States Circuit Judge

April 4, 2013