UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS

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

OPINION OF JUNE 12, 2013

On June 7, 2013, I conducted a hearing to resolve a *Daubert* challenge to Dr. Jerry Ruth, and to hear argument on the motions by Promega and the defendants (whom I'll refer to collectively as Life Tech) for summary judgment on infringement, damages, and validity. On the basis of that hearing and the motions, I grant summary judgment that claims 62 (and claim 62's dependent claims), 66, and 67 of U.S. Patent No. RE43,096—the '096 patent that Promega challenges and Life Tech seeks to enforce—are invalid. These rulings require entry of judgment in favor of Promega; the judgment order will be issued as soon as this opinion is docketed. For completeness I also discuss in this opinion the summary judgment motions dealing with infringement and with damages.

Daubert challenge to Jerry Ruth.

Dr. Ruth, a highly-qualified biochemistry research scientist, has opined that the asserted claims of the '096 patent are invalid as anticipated by, or obvious in light of, prior art. Life Tech has moved to exclude his opinions and testimony on the authority of Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 591–92 (1993). Ruth's report emphasized a 1986 article in *Nature* coauthored by Lloyd Smith, one of the '096 inventors. But he now concedes that the article is not prior art, and therefore irrelevant, because it postdates the patent's priority date of January 16, 1984.

Life Tech challenges Ruth's analysis of other prior art, including U.S. Patent No. 5,118,800 (the "Smith '800 patent"), as hastily articulated, vague, and conclusory. That characterization is inaccurate; Ruth's report analyzes at length the prior art that Promega contends invalidates the '096 claims and describes the parts of those references

that he believes an ordinarily skilled biochemist would have known to combine in order to be able to practice the disputed claims of the '096 patent. So had this case gone to trial, Ruth would have been allowed to testify as an expert witness except with regard to Smith's article.

Infringement.

I can dispose of the infringement and damages issues very briefly and so will begin with them. Life Tech has moved for summary judgment that Promega's manufacture, testing, and sale of various products directly infringe claims 62, 66, and 67 of the '096 patent and that Promega is additionally liable for having induced its customers to infringe the same claims by using its products. See 35 U.S.C. §§ 271(a), (b), (f). Life Tech's submission at dkt. 397-1 outlines the specific products in question and the manner in which Life Tech contends that they infringe each claim. "To streamline the case so there will not be a dispute on infringement," Promega now concedes Life Tech's contentions regarding infringement with two reservations with which Life Tech doesn't quarrel. The first is that if only claim 62 is valid, Promega denies liability for inducing infringement by foreign customers, see 35 U.S.C. § 271(f), because that section does not cover method claims. *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 576 F.3d 1348, 1359 (Fed. Cir. 2009) (en banc). Second, Promega's products that do not use four sets of fluorescent tags do not infringe claim 67. Those concessions resolve any disputes about infringement.

Damages.

Jed Greene, Life Tech's damages expert, wanted to testify that 10 percent would be the proper royalty rate applicable to sales of products found to infringe '096 if the relevant claims of the patent are valid. On the basis of Greene's testimony at the *Daubert* hearing, I ruled that he would not be allowed to testify about royalty rate. Carl Degen, Promega's damages expert, had in various places in his expert report, deposition, and *Daubert* testimony indicated that he thought the reasonable range for the royalty rate would be 2 to 4.4 percent. Life Tech asks me to treat this as a concession by Promega that 4.4 percent is a reasonable rate, and notes that the figure is derived in part from evidence given by Life Tech's chief technical officer, Randall Dimond.

I am sympathetic to the proposition that if a defendant concedes a reasonable range for a royalty rate, the plaintiff (if it proves liability) should be entitled to the top of the range if, as in this case, there is no evidence that would permit a jury to select a point within that range as being the most reasonable damages estimate. This approach would be consistent with case law that, while insisting that injury be proved in the usual way, permits doubts about the amount of damages to be, within reason (obviously an essential, and sometimes overlooked, qualification), resolved in the plaintiff's favor. See, e.g., *Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555, 562–63 (1931); *Datascope*

Corp. v. SMEC, Inc., 879 F.2d 820, 826 n. 6 (Fed. Cir. 1989). This approach is appropriate because invariably the violation of the defendant's rights will have made an exact calculation of damages difficult and often impossible.

But I don't think Degen's testimony and proposed testimony considered as a whole constitute a concession that the reasonable royalty should be 4.4 percent; he also offers reasons why a jury could come to 2 percent. For while he indeed derived the 4.4 percent figure from Dimond's evidence of Promega's charging a higher royalty, he also expressed disagreement with Life Tech's interpretation of that evidence. That disagreement itself requires some explaining.

In 2006, Promega and Life Tech settled litigation over genetic-identity products that used technology patented by both companies. Promega agreed to pay Life Tech a 2 percent royalty for use of Life Tech's '096 patent if the patent was reissued (as it was); Life Tech agreed to pay a 5.5 percent royalty for use of Promega's STR ("short tandem repeat") patents; Life Tech promised to maintain the compatibility of its machines with Promega's products (chemicals used with those machines).

Dimond has testified that Promega's STR patents would have commanded a 12 percent royalty in a one-way license deal (he implies others had paid that rate) but had reduced the rate to 5.5 percent in exchange for Life Tech's promise to maintain its machines' compatibility with Promega's products. Degen likes this explanation of the discount because if that promise was responsible for the rate, no other terms of the 2006 agreement, including Life Tech's 2 percent royalty, would be affected. So Degen argues 2 percent would be the right royalty rate to expect the parties to have agreed on in 2012 with respect to Promega products outside the field of use governed by the 2006 cross-license.

Life Tech disagrees. Its position is that Promega accepted a lower rate in exchange for getting its own lower rate, implying that the 2 percent rate was also lower than Life Tech would grant in a single-license deal, that is, a deal in 2012 allowing Promega to use Life Tech's patent in Promega products outside the field of use of the 2006 license.

Degen's 4.4 percent calculation is a back up, lest the trier of fact think 2 percent too low, in which event Degen wants the trier to assume for argument's sake that in the cross-license negotiation in 2006 each party gave the other the same percentage discount. Promega discounted its normal 12 percent rate to 5.5 percent, a 54 percent discount, implying (given the assumption of identical discounts) that Life Tech accepted a 54 percent discount; and if 2 percent is a 54 percent discount from Life Tech's standalone royalty rate, that rate was 4.4 percent. But this as I said is Degen's (and Promega's) back-up position. His (and its) preferred interpretation is that the proper royalty damages rate is only 2 percent, and he could so testify were there a trial on damages, subject of course to cross examination of his testimony on his opinion, including the 4.4 percent alternative.

I want to discuss one more issue that in view of my analysis of validity is not dispositive:

"Specifically hybridized."

In order to preserve a record for appeal, Promega continues to press its challenge to the construction of the term "specifically hybridized" (i.e., designed to bind to) in my April 4 and May 27 orders, in which I construed the term to cover all oligonucleotides intended to bind to a specific location on a complementary strand of DNA even if that location is not unique. Promega argues that the term means "binding to one and only one location on a complementary strand of DNA."

Promega complains that it had no opportunity to brief construction of this claim term, but it could and should have made all the arguments it now seeks to make in earlier submissions. When Life Tech moved for summary judgment that Promega's Power Plex 16 HS system infringes the '096 patent, Promega argued that the Power Plex 16 HS system doesn't infringe because its oligonucleotides can bind to multiple sites on the complementary DNA strand and therefore aren't specifically hybridized, which Promega defines as meaning that the oligonucleotide must bind to a unique site. My ruling on that summary judgment motion required me to interpret the term, and I rejected Promega's construction. My prior orders explain why Promega's construction is unreasonably narrow.

Turning now to the dispositive issue, that of validity, I need to address a series of sub-issues, beginning with—

Anticipation, Obviousness, and Obviousness-Type Double Patenting.

Ordinarily the jury resolves all factual disputes relevant to validity, e.g. *SynQor, Inc. v. Artesyn Technologies, Inc.*, 709 F.3d 1365, 1373 (Fed. Cir. 2013), but if the facts are undisputed (in the sense either that the parties agree on the material facts, or that there could be no reasonable disagreement over what they are, given the record in the case), the judge decides the case, ordinarily on the basis of a motion for summary judgment. See, e.g., *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 427 (2007); *OSRAM Sylvania, Inc. v. American Induction Technologies, Inc.*, 701 F.3d 698, 704 (Fed. Cir. 2012); *MySpace Inc. v. GraphOn Corp.*, 672 F.3d 1250, 1257 (Fed. Cir. 2012).

Promega seeks summary judgment on the basis of the doctrines of anticipation and obviousness. In addition, I requested and received briefing on the claims' validity under the doctrine of obviousness-type double patenting.

Promega's arguments for anticipation and obviousness rely in large part on the '800 patent, which claims the chemical structure of a linker arm that can be used to attach a fluorophore to an oligonucleotide. The '800 patent shares a common inventor with the '096 patent, so Life Tech argues that it is not prior art, see 35 U.S.C. § 102(e)(2), and al-

ternatively that if it is prior art it may not be considered for purposes of determining obviousness. See 35 U.S.C. § 103(c)(3).

The Smith '800 Patent is Prior Art. Prior art includes "a patent granted on an application…*by another* filed…before the invention by the applicant." 35 U.S.C. § 102(e)(2) (2011) (emphasis added). The application leading to the issuance of the '800 patent (No. 06/565,010) was filed on December 20, 1983, one month before the application for the '096 patent.

If the inventors on two applications are different, then one patent is owned by one inventor and the other patent by the other inventor. *In re Kaplan*, 789 F.2d 1574, 1575 (Fed. Cir. 1986); *Application of Land*, 368 F.2d 866, 876–79 (C.C.P.A. 1966); 3 *Chisum on Patents* § 3.08(a) (2013). And if there are two inventors on one application and two other inventors on the other, each pair is the owner of one of the patents. Although Lloyd Smith is listed as an inventor of both the '096 and '800 patents, the '096 lists four additional inventors (Lee Hood, Michael Hunkapiller, Tim Hunkapiller, and Charles Connell); the '800 therefore belongs to "another" (that is, another inventing entity from the inventing entity of the '096) and thus can be prior art used to challenge the validity of the '096.

When research by a single research *team* results in multiple patent applications listing different inventors, the inventor of one of the patents can avoid having the patent applications from other inventors on their team treated as prior art by establishing an earlier priority date, and he can do by proving that he reduced his invention to practice before the patent application or applications filed by the other inventors. See, e.g., *Applied Materials, Inc. v. Gemini Research Corp.*, 835 F.2d 279, 281 (Fed. Cir. 1987). Thus, patent applications from related inventors avoid invalidating each other not through the "of another" requirement (for different inventors are always "another," or more precisely "others"), but through the rule that assigns a priority date based on when the invention was made rather than when the patent application was filed. Since the '800 and '096 patent applications were filed just one month apart, the technology patented in the '096 may have been invented before the '800 patent application was filed, which would prevent the '800 patent from being used as prior art to challenge the validity of the '096 patent even though the inventors were not identical.

But Life Tech has waived any argument for an earlier priority date for the '096. It moved for summary judgment that the priority date is January 16, 1984, [dkt. 211], which of course is after December 20, 1983; denied that there was any evidence of an earlier date in its interrogatory responses; and failed to amend those responses in timely fashion. See my Order of June 4, 2013, dkt. 437. The priority date of the '096 patent is therefore January 16, 1984, making the '800 patent prior art. 35 U.S.C. § 102(e).

The Smith '800 Patent Does not Qualify for the § 103(c) Safe Harbor. Prior art under section 102(e) that does not anticipate a patent claim may nonetheless render the claim obvious under 35 U.S.C. § 103. But there is a safe harbor, designed to encourage (or at least not penalize) team research, 35 U.S.C. § 103(c); *OddzOn Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1403 (Fed. Cir. 1997); *In re Longi*, 759 F.2d 887, 894 (Fed. Cir. 1985): an earlier patent application filed by another inventor, although prior art under section 102(e), will not render a later patent obvious if both patents were "owned by the same person or subject to an obligation of assignment to the same person." 35 U.S.C. § 103(c)(1) (2012). "The statute is directed to situations of common ownership," *In re Hubbell*, 709 F.3d 1140, 1153 (Fed. Cir. 2013), and thus requires that both patents be "entirely or wholly owned by" or assigned (or contractually obliged to be assigned) to the same entity. Manual of Patent Examining Procedure § 706.02(l)(2)(I). "If the person(s) or organization(s) owned less than 100 percent of the subject matter which would otherwise be prior art to the claimed invention, or less than 100 percent of the claimed invention, then common ownership would not exist." *Id.*

Section 103(c) looks to the alleged patent owner's rights "at the time the claimed invention was made." 35 U.S.C. § 103(c)(1) (2012). Life Tech argues that as of January 16, 1984, Caltech was the sole owner of the patents. For before that date Smith had assigned the rights to the '800 patent to the university and the 1984 application that led to the '096 patent had four inventors originally, all of whom also assigned their rights to the university before January 16, 1984 [dkt. 468-2]. But the '096 patent had five inventors, for in 1988 Caltech had petitioned the PTO to add Charles Connell as an inventor, and the petition had been granted [dkt. 199-7, PROM008425-30]. The inventors listed on a patent must include everyone who contributed to and thus has legal rights in the invention, because you cannot patent material if you "did not [yourself] invent the subject matter sought to be patented," 35 U.S.C. § 102(f) (2004); *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1349 (Fed. Cir. 1998); 1-2 *Chisum on Patents* § 2.03 (2013) ("the originality requirement bars issuance of a patent to a person or persons who derive the conception of the invention from any other source or person"). Life Tech argued that Connell had contributed to the invention and therefore had to be added to the patent. But he didn't assign his patent rights to Caltech until 1988. Having conceded that Connell is a necessary inventor of the patent, Life Tech cannot now argue that Caltech had full ownership rights to the invention before Connell assigned his rights to the university in 1988.

Like many research institutions, Caltech has long required its employees to assign to it the rights to any invention made using university resources. "All employees are required to sign a patent agreement assigning their rights to inventions which they may make in the line of duty, on Institute time, or with Institute facilities to the Institute or its nominee." California Institute of Technology Staff Personnel Memoranda, Subject: Patent Policy, Section 2.a.(1) (1977) [dkt. 459]. But Connell was employed by Applied Biosystems, never by Caltech. Life Tech presents no evidence that he was required to

assign his rights to Caltech at the time of invention. And one month after filing the initial application for the '096 patent in February 1984, the university represented to the PTO that it shared ownership with Applied Biosystems. [dkt. 199-4, p. 39]. In sum, the university was not the sole owner of the patented invention at the time of invention. Section 103(c)(1) therefore does not apply.

It is true that under the version of § 103(c) in effect when the '096 patent was reissued, research stemming from "a joint research agreement that was in effect on or before the date the claimed invention was made" could nonetheless be "deemed to have been owned by the same person or subject to an obligation of assignment" when certain conditions were met. 35 U.S.C. § 103(c)(2) (2012). But "joint research agreement" is limited to "a written contract, grant, or cooperative agreement." 35 U.S.C. § 103(c)(3) (2012). Although Life Tech has proved that Caltech and Applied Biosystems collaborated during the 1980s—Lloyd Smith, for example, worked as an independent consultant for Applied Biosystems—it has not identified any written joint research agreement covering the invention, or argued that such a written agreement exists or ever existed. Because section 103(c) therefore does nothing for Life Tech, I do not reach Promega's argument that section 103(c) is inapplicable because the '096 patent stems from a patent application that dates back to 1984.

With 103(c) not applying, the '800 patent is prior art for both anticipation under § 102(e) and obviousness under § 103. I have now to consider whether either or both of these doctrines invalidate claims in the '096 patent.

Anticipation. Because the Smith '800 patent is prior art, it will anticipate—and therefore render invalid—a claim of the '096 patent if "each and every element as set forth in the claim is found, either expressly or inherently described" in its specification. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). An element is described if it "is necessarily present in the thing described in [a prior art] reference, and…would be so recognized by persons of ordinary skill." *Id.* Anticipation is a question of fact, but summary judgment is appropriate if there is no genuine dispute of material fact. *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1327 (Fed. Cir. 2001).

The '800 patent describes the chemical structure of a linker arm and the use of that linker arm to attach a fluorophore to an oligonucleotide. (3:60–64; 5:50–51) It also describes the use of these fluorescently tagged oligonucleotides in DNA sequencing: "the synthesis of fluorescent-labeled oligonucleotides permits the automation of the DNA sequencing process" (3:64–68) and the labeled oligonucleotides "are effective in DNA hybridization methods, as illustrated by their use as primers in DNA sequence analysis." (5:51–55). Smith acknowledged at his deposition that these references to DNA sequencing describe the Sanger method. Smith deposition, May 28, 2013 (dkt. 392), at 151:26–154:10. The Sanger method was invented in 1977 as a way to perform DNA sequencing—determining the specific order of nucleotides in a target strand of DNA. A

known DNA sequence called a cloning vector is attached to the target strand. An oligonucleotide designed to bind to the cloning vector is tagged so that it will be detectable at a later stage in the sequencing. The oligonucleotide binds to the cloning vector, forming a "duplex"—a double-stranded DNA molecule. A chemical called a polymerase is introduced to catalyze the extension of the oligonucleotide along the complementary strand. Modified nucleotides associated with a particular nucleic acid base are added to the end of the strand to prevent additional nucleotides from binding. The result is strands of different lengths ending in a particular base; the lengths of the strands are then measured to determine the sequence of nucleotide bases in the target strand. A person skilled in the art would have recognized the reference to the Sanger method, would be familiar with the steps of that method, see Dovichi rebuttal report, Jan. 15, 2013 (dkt. 297), at ¶¶ 40–41, and would therefore understand those steps to be a necessary part of the '800 patent specification.

The Sanger method was widely used in the early 1980s. Dovichi deposition, May 6, 2013 (dkt. 392), at 137:9–12. At the time, oligonucleotides were tagged using radioactive labels, but these were expensive, required costly safety precautions, and could not be read reliably by a computer. It was widely understood that fluorescent tags ("fluorophores") would be preferable on all three counts (U.S. Patent No. 4,948,882 ("Ruth '882 patent") at 1:43–2:2). But fluorescent tags, unlike radioactive ones, might interfere with the chemical reactions in Sanger sequencing. The research leading to the '800 patent solved this problem: Smith and other Caltech researchers used a linker arm with a specific chemical structure to attach a fluorophore to the oligonucleotide in a way that didn't interfere with the binding and extension processes and that could therefore be used in the Sanger method.

In December 1983 Smith applied for a patent (the '800 patent) on the linker arm. The specification of this patent stated that the linker arm could attach a fluorophore to an oligonucleotide, which could then be used in the Sanger method (3:64–68; 5:51–55). In January 1984, Smith and others filed a second application, which became the '096 patent. This application described the use of an oligonucleotide tagged with the linker arm for use in the Sanger method. The '096 patent resulted from the same line of research as the '800 patent, and Promega contends that the asserted claims of the '096 are anticipated by the '800. I discuss those three claims in turn.

Claim 62 (and its dependent claims). In describing the use of fluorescently tagged oligonucleotides to perform Sanger sequencing, the '800 patent either expressly or inherently discloses every element of claim 62—which describes:

> 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 complemen-

> tary strand of DNA, and wherein the oligonucleotide is covalently coupled to a fluorophore so as to allow chain extension by the polymerase.

The '800 patent discloses an "oligonucleotide…covalently coupled to a fluorophore." Each of the claimed linker arms is a covalent coupling that can attach an oligonucleotide to a fluorophore (35:1–38:5). Each of the additional elements of the claim is inherently present in the Sanger method, in the sense that a person skilled in the art would understand the presence of those elements to be necessarily implied by the patent's references to the use of the described oligonucleotides in DNA sequencing. Sanger sequencing is "a method of nucleic acid sequence analysis" that, as I have explained, necessarily involves "extending" the disclosed, fluorescently-tagged 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 when a linker arm is used, it must necessarily "allow chain extension by the polymerase" in order to function effectively in Sanger sequencing. The resulting "extension product" will be "labeled" because of the attached fluorophore.

Life Tech disputes none of this. Asked at the summary judgment hearing to explain why the '096 patent represents an advance over the '800, it said only (so far as relates to claim 62) that the '096 patent contains "an example of actually generating sequence information by using the oligonucleotides." But the '800 patent states that the oligonucleotides it describes "are effective" in sequencing, not that they could become so only after further research (5:51–55); and so the absence of an example from the specification of the '800 is irrelevant. Specifically, the oligonucleotides are "effective" by reason of their "use as primers in DNA sequence analysis" (*id*.). Life Tech's brief says that the '800 patent "claims a fundamentally different invention" from the '096 patent, but the specification describes the use of the linker arms in Sanger sequencing, and that shows that the '800 anticipates claim 62 of the '096.

Promega's experts have not said that the '800 patent anticipates the '096 patent. But expert witnesses are not required, and normally are not expected, to offer legal conclusions. The experts' reports discuss the relevant portions of the '800 patent and explain their overlap with the '096, and that's sufficient. Life Tech points out that claim 62 covers more than Sanger sequencing reactions that use the Smith '800 linker arm; it covers all methods of nucleic acid sequence analysis and all linker arms that allow the oligonucleotide to hybridize and extend. But a prior art reference that discloses a particular species anticipates the genus (in this case, all methods of nucleic acid sequence analysis) to which the species belongs. *In re Gosteli*, 872 F.2d 1008, 1010 (Fed. Cir. 1989); *In re Slayter*, 276 F.2d 408, 411 (C.C.P.A. 1960).

Promega argues that the '800 patent also anticipates the dependent claims of claim 62. Those claims are:

> 63. The method of claim 62, further comprising separating said labeled extension product from said duplex.
>
> 65. The method of claim 64 or claim 62, wherein the fluorophore is covalently coupled to the oligonucleotide through an amine linkage. [Life Tech appears to assert this claim only as a dependent claim of claim 62.]
>
> 70. The method of claim 62, wherein substantially all molecules of the labeled extension product individually comprise a single fluorescent nucleotide.
>
> 74. The method of claim 62, wherein substantially all molecules of the labeled extension product are individually coupled to a fluorophore by a single covalent linkage.
>
> 80. The method of claim 74, wherein substantially all molecules of the labeled extension product individually are terminally labeled with a fluorophore.
>
> 86. The method of claim 70, wherein substantially all molecules of the labeled extension product individually are terminally labeled with a fluorophore.
>
> 92. The method of claim 74, wherein substantially all molecules of the labeled extension product individually comprise a 5' terminal fluorescent nucleotide.
>
> 98. The method of claim 86, wherein substantially all molecules of the labeled extension product individually comprise a 5' terminal fluorescent nucleotide.

The additional elements of the claims dependent on claim 62 are also found in the '800 specification. Sanger sequencing requires that the labeled oligonucleotide be "separated" from the duplex (claim 63). The linker arms claimed in the '800 patent are amine linkages (claim 65), Dovichi rebuttal report, Jan. 15, 2013 (dkt. 297), at ¶ 93, and they connect a single fluorophore to a single nucleotide at the 5' terminal end of the oligonucleotide (claims 70, 74, 80, 86, 92, and 98). *Id*. Dovichi rebuttal report, Jan. 15, 2013 (dkt. 297), at ¶ 93. The dependent claims are therefore also anticipated.

Claim 66. Claim 66 describes:

> 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.

As I've already pointed out, the '800 patent discloses an "oligonucleotide…covalently coupled to a fluorophore," which would necessarily "allow chain extension by the polymerase" if used in Sanger sequencing. The remaining portion of claim 66—"a mixture comprising a polymerase and a duplex, wherein the duplex comprises an oligonucleotide specifically hybridized to a complementary strand of DNA"—is necessarily formed during Sanger sequencing. Claim 66 claims the mixture that results when a method of sequence analysis described in claim 62 is performed with a fluorescently tagged oligonucleotide, as the '800 patent instructs. Because the '800 patent either expressly or inherently discloses every limitation of claim 62, it discloses every limitation of claim 66 as well. Claim 66 is therefore anticipated by the '800 patent.

Claim 67. Claim 67 recites:

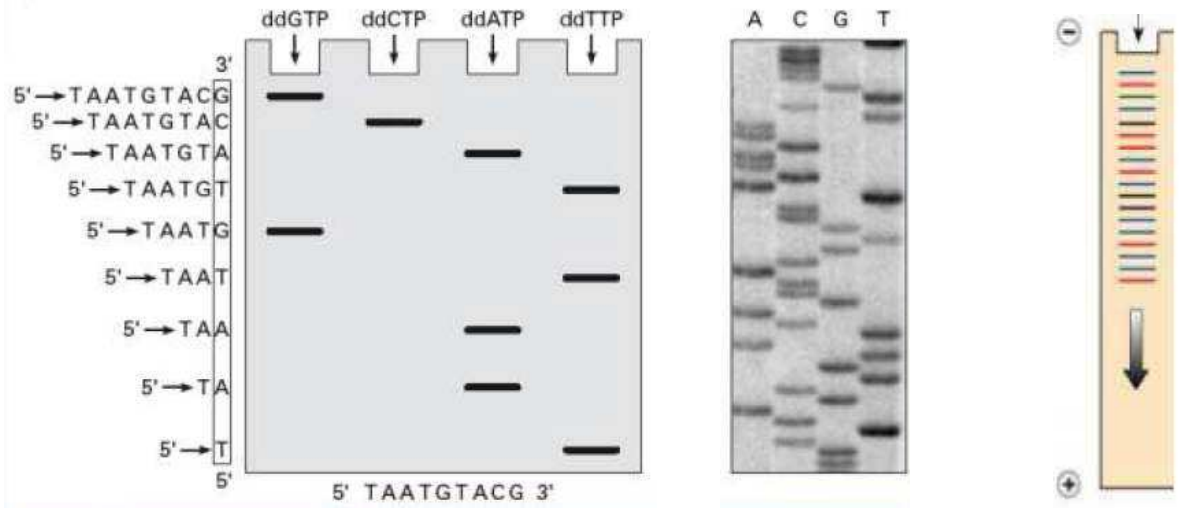
> A composition comprising four sets of oligonucleotides, wherein oligonucleotides of each of the four sets are distinguishably labeled with a different type of fluorophore from the oligonucleotides of the other three sets.

Promega argues that this claim is anticipated by the '800 patent. It points out that fluorescent Sanger sequencing, disclosed in the '800 patent, involves four separate reactions, and suggests that four distinguishable fluorophores, in four different colors, are needed to distinguish the results of the four reactions. That's not the case: as I explain below, the outputs of the four reactions could be kept separate and measured on four different gel tracks, in which event only a single color would be necessary. The '800 patent does not anticipate claim 67.

Obviousness. But it may render it obvious; and other prior art references, such as the Ruth '882 patent, might do this as well. Like claims 62 and 66, claim 67 requires fluorescently tagged oligonucleotides, but unlike those claims it does not require that the oligonucleotides be extendable. Many prior art references—such as the Ruth '882 patent, the application for which was filed in February 1983—explained how to attach fluorescent tags to oligonucleotides, even though it was uncertain whether the resulting oligonucleotides could always be extended. See Ruth report, Dec. 7, 2012 (dkt. 290-1), at 19–23; Dovichi deposition, May 6, 2013 (dkt. 390), at 267:16–19 ("there's a long and rich history…of people who employed fluorescently labeled oligonucleotides"). This could be done using fluorophores with many different spectra—colors distinct enough from each other to be distinguishable by a computer (Ruth '882 patent, 3:56-4:3). So a person of ordinary skill would have found it straightforward to tag four different sets of oligonucleotides with four distinguishable fluorophores.

The more difficult question is whether such a person would have been motivated to do this. The prior art need not contain an explicit "teaching, suggestion, or motivation

to combine known elements" for a claim to be obvious, but a person of skill must have had "an apparent reason to combine the known elements in the fashion claimed by the patent." *KSR International Co. v. Teleflex, Inc.*, *supra*, 550 U.S. at 418. The reason biochemists would mix four distinguishable sets of fluorophores in Sanger sequencing is to avoid having to run four separate reactions to measure the tagged DNA strands. Remember that Sanger sequencing requires creating and measuring DNA strands of different lengths ending in the same nucleotide base. The strands are measured using a process called "electrophoresis"—they are placed in a gel and separated by length with an electric current. The distance that each oligonucleotide travels across the gel indicates the length of the strand, revealing the position of the nucleotide base at the end of the strand. For example, by creating strands ending in the nucleotide thymine (T) and running those strands through electrophoresis, one can identify all thymine bases in the DNA sequence. This operation must be performed four separate times for each target strand—once for each possible nucleotide bases (A, C, G, and T)—to reveal the identity of each base in the DNA sequence. If radioactive tags, or fluorescent tags of a single color, are used, all of the bases give off the same signal, so scientists must keep the four bases separate by running the oligonucleotides on four different gel tracks. (A diagram of this process is shown at left below, and an actual example at center.) But if a different color is used for each base, the four bases emit different signals and a single track can be used (illustrated at right below), reducing time and expense.



Mixing four sets of fluorescent oligonucleotides is therefore useful in fluorescent Sanger sequencing. But even before Caltech researchers developed that process, fluorescent oligonucleotides were useful for other types of reactions. An oligonucleotide described in the Ruth '882 patent could bind to a strand of DNA with a complementary sequence and if tagged could thus indicate whether the complementary sequence appeared on a target strand of DNA. These DNA "probes" were valuable well before fluo-

rescent sequencing was developed; Dovichi notes, for example, that they were key to a common technique called "Southern blotting," published in 1975. Dovichi rebuttal report, Jan. 15, 2013 (dkt. 297), at ¶ 36. Electrophoresis could be used to analyze these oligonucleotides, but researchers would have liked to analyze multiple strands at once and so would have sought a single-gel advance in technology even before 1984.

Promega points to evidence that researchers were aware of the potential benefits of multicolor tags even for non-sequencing uses. A 1982 research abstract noted that "a lot of information can be obtained form [*sic*] one column by using multi-color labeling. Now we are developing an automated real time fluorescence detection gel electrophoresis system." Masao Tsuchiya, Yuzuru Hushimi, and Yasunori Kinishita, "Fluorescent Labelling of DNA and Real Time Fluorescence Detection Gel Electrophoresis," 22 *Biophysics* supp., No. 2-E-19 (Sep. 25, 1982); see also Ruth report at 26–28. The abstract described this as an important development, although it could not be used for fluorescent sequencing because no one had yet published such a sequencing method. A person of ordinary skill who read the abstract would have been motivated to use its multicolor technique when analyzing DNA probes, in order to increase the number of probes he could process on a single gel. Leroy Hood, an inventor of the '096 patent, explained at his deposition that a person of ordinary skill in the art would have wanted to use multiple fluorescent tags in 1984 for non-sequencing reactions: "If you had 100,000 fragments that you'd like to map, being able to multi-plex and have a quarter as many measurement reactions for them would be very attractive…. [With] four different fluorescent dyes[, you] could multiplex four clones at a time to do the mapping, labeling each of the fragments from the clones with a different colored dye. It's exactly like the sequencing reactions." Hood deposition, May 23, 2013 (dkt. 391), at 37:4–20. Life Tech offers nothing to contradict this evidence that a person of ordinary skill would have had "an apparent reason" to attach different tags to four groups of oligonucleotides and mix them.

What are called "secondary considerations" are relevant to obviousness. If for example the market and the research community ignored a prior art reference but reacted quickly to the disclosure of the patented invention, that would be evidence that the earlier reference had not rendered the invention obvious—that the patent had revealed important information. Dovichi, Life Tech's expert on secondary considerations of non-obviousness, wanted to be permitted to testify that the Smith 1986 paper, which announced the inventions claimed in the '096 patent, was widely praised by biochemists, suggesting that the paper reported a major advance. I refused to allow him to so testify, because his only evidence of "praise" was the number of citations to the paper, and he neither distinguished positive from negative citations nor compared the total number to the number of citations to papers acknowledged to have announced major advances. He also had not attempted to allocate citations among different claims or concepts in the '096 patent. Life Tech has not shown that the biochemists who cited the Smith paper

considered the concept of using four fluorophores in oligonucleotide analysis to be novel: they might instead have been responding to the description of fluorescent Sanger sequencing, which was contained in the '800 patent. I was not impressed that Dovichi considered the total number of citations to the Smith paper—983—too many for him to read. No doubt. But he could have read a random sample of them to determine both the percentage of positive citations and which concepts if any the authors of the citing papers considered novel in the Smith paper. Also his expert report offered no opinion specific to claim 67. Nor does Life Tech present any other such evidence.

With such meager evidence, secondary considerations fall out of the case, leaving uncontested the facts—specifically the disclosure of fluorescent tags in the Ruth '882 patent and multicolor analysis in the research abstract—that demonstrate that the invention was obvious, thus warranting summary judgment. *KSR Int'l Co. v. Teleflex, Inc.*, *supra*, 550 U.S. at 427; *Tokai Corp. v. Easton Enterprises, Inc.*, 632 F.3d 1358, 1366, 1370–73 (Fed. Cir. 2011).

Obviousness-type Double Patenting. Even if the '800 patent were not prior art and therefore did not anticipate or render obvious the asserted claims of the '096 patent, it might nonetheless invalidate those claims under the doctrine of obviousness-type double patenting. I asked the parties to brief this issue and now address it pursuant to Fed. R. Civ. P. 56(f)(2), which permits a judge, after giving notice and a reasonable time to respond, to grant summary judgment "on grounds not raised by a party." Life Tech's argument that Promega has waived the double-patenting argument is therefore unavailing.

A patent application is not anticipated or rendered obvious by a prior application by the same inventor. But this rule unless qualified would open a loophole allowing a patentee to obtain a patent term in excess of the statutory period (in our case, 17 years from issuance) by patenting overlapping claims. It's true that an inventor is entitled to "*a* patent" on an invention, 35 U.S.C. § 101 (emphasis added), and therefore may not file identical claims, *In re Goodman*, 11 F.3d 1046, 1052 (Fed. Cir. 1993), but the claims need not be identical to pose a problem. Suppose a medical researcher invents a pill for use in a specific medical treatment. The researcher receives a patent in 1992 claiming the pill, and another in 2001 claiming the use of the pill in the medical treatment for which the pill was invented. No one could use the pill without infringing both claims, and so if the second claim remained enforceable after the first claim had expired the researcher would have received a patent term of more than 17 years.

The doctrine of obviousness-type double patenting plugs the loophole. A court may not allow a later claim by the same inventor if the earlier one is "so alike that granting both exclusive rights would effectively extend the life of patent protection"—with "so alike" meaning that the earlier claim anticipates or renders obvious the later one. *Pericone v. Medicis Pharmaceutical Corp.*, 432 F.3d 1368, 1373 (Fed. Cir. 2005); see also *Eli*

Lilly & Co. v. Barr Labs, Inc., 251 F.3d 955, 968 (Fed. Cir. 2001). Because the doctrine is meant to prevent an inventor from extending the life of his patent by means of patents subject to different terms for different claims covering the same innovation, the doctrine turns on what is claimed in the earlier patent. Double-patenting cases thus ordinarily require the court to construe the claims of the first patent so that they can be compared to the claims of the later one. *Id*. at 968. But the claims of the '800 patent are straightforward; neither party has identified terms in that patent that require judicial construction. Claim 1 describes "the oligonucleotide compound having the formula: [chemical diagram], wherein B is selected from the group consisting of a nucleoside base and their derivatives." The other claims are similar.

A claim in a later patent escapes the double-patenting rule even if the innovation is disclosed in the specification of the earlier patent, provided that it's not disclosed in the claims. *In re Kaplan*, *supra*, 789 F.2d at 1580. Life Tech argues that because the sequencing method is not explicitly described in the '800 claims, the doctrine of double patenting does not apply. But the court may examine the specification and other evidence to determine whether an application of an earlier claim would have been obvious. *Eli Lilly & Co. v. Teva Patenteral Medicines, Inc.*, 689 F.3d 1368, 1379–80 (Fed. Cir. 2012); *Otsuka Pharmaceutical Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1298 (Fed. Cir. 2012). So I can consider the '800 specification's description of Sanger sequencing reactions involving certain linker arms. I must determine whether those reactions were an obvious application of the '800 claims.

Claim 62 and dependent claims. Recall that claim 62 describes "a method of nucleic acid sequence analysis" that uses an oligonucleotide with various properties. This method claim differs in three ways from claim 1 of the '800 patent: it involves any linkage ("covalent coupling") that allows the oligonucleotide to be specifically hybridized and extended, while the '800 patent claims only certain linker arms with these properties; it requires that the oligonucleotide bind to a fluorophore (via the linkage); and it claims a method of nucleic acid sequence analysis in which the oligonucleotide is hybridized and extended. But these differences are obvious and so invalidate claim 62 under the double-patenting doctrine. The requirement of a "method of nucleic acid sequence analysis" is satisfied by the pre-existing knowledge of Sanger sequencing. Because of the heightened interest in fluorescent tags, a person of ordinary skill would as I have already explained have found it obvious to attach a fluorophore to the linker arm if the resulting oligonucleotide would be effective in Sanger sequencing. And the specification of the '800 patent makes clear that each linker arm claimed by that patent was effective in that respect: it could connect a fluorophore to an oligonucleotide in such a way that it could be extended and used in sequence analysis. It is true that some chemical linkages not claimed in the '800 patent are also effective in sequencing. But claim 62 covers a genus—methods of sequence analysis that involve certain chemical linkages—

and by making clear that at least one such linkage existed the '800 patent rendered that genus obvious. "A later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim." *Eli Lilly & Co. v. Barr Laboratories, Inc.*, *supra*, 251 F.3d at 971.

Life Tech objects that without the specification of the '800 patent, a person of ordinary skill would not have known that the claimed linker arms were effective in sequencing. But claim 62 covers the main intended use of the linker arms. Double patenting "encompasses any use for a compound that is disclosed in the specification of an earlier patent claiming the compound and is later claimed as a method of using that compound." *Sun Pharmaceutical Industries v. Eli Lilly & Co.*, 611 F.3d 1381, 1386 (Fed. Cir. 2010). Upholding claim 62 would deny the public the benefits of the main use of the '800 claims after the full term of the '800 patent had expired. "It would shock one's sense of justice if an inventor could receive a patent upon a composition of matter, setting out at length in the specification the useful purposes of such composition, manufacture and sell it to the public, and then prevent the public from making any beneficial use of such product by securing patents upon each of the uses to which it may be adapted." *Eli Lilly & Co. v. Teva Patenteral Medicines, Inc.*, *supra*, 689 F.3d at 1379 (quoting *In re Byck*, 48 F.2d 665, 666 (C.C.P.A. 1931)).

Ordinarily when one of an inventor's patents invalidates another because of obviousness-type double patenting the inventor can file a "terminal disclaimer," which preserves his right to enforce the second patent until the date the first patent expires. 35 U.S.C. § 253; *Perricone v. Medicis Pharmaceutical Corp.*, *supra*, 432 F.3d at 1375. But because the '800 patent expired in 2009 and the '096 patent was not reissued until 2012 and Life Tech can seek damages only for infringement after that date, it cannot use a terminal disclaimer to avoid the application of the double-patenting doctrine.

I conclude that claim 62 is made obvious by the claims of the '800 patent and is therefore invalid under the doctrine of obviousness-type double patenting. Life Tech does not identify any additional elements of the dependent claims that would not have been obvious to a person of skill in the art, and so those claims are invalid as well.

Claim 66. Claim 66 is a composition claim (unlike claim 62, a method claim). Like 62, claim 66 differs from the claims in the '800 patent in including any linker arm that allows an oligonucleotide to be specifically hybridized and extended, rather than only certain linker arms with this property. But as I have explained, by claiming a species of linker arms that are effective in sequencing the '800 renders obvious the genus of all linker arms with these properties. Claim 66 also requires that the oligonucleotide be covalently coupled to a fluorophore; that it hybridize to a complementary strand of DNA to form a duplex; and that it be part of the same mixture as a polymerase. All these are implications of using the oligonucleotide in Sanger sequencing.

Essentially claim 66 covers a mixture that contains a linker arm described in the '800 patent (or a similar linker arm), which is produced by using the linker arm in sequencing, as the specification of the '800 patent directs. By claiming a mixture necessarily produced by a given method, claim 66 restricts the public's access to the method just as claim 62, which covers the method itself, does; and the doctrine of double patenting is equally applicable in such a situation. Claim 66 is therefore obvious under the claims of the '800 patent and invalid under the doctrine of double patenting.

Written description and enablement.

Promega seeks summary judgment that claims 62 (and its dependent claims) and 66 flunk the written description and enablement requirements, 35 U.S.C. § 112, on two grounds. "Compliance with the written description requirement is a question of fact but is amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving party." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir. 2008); see also *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1072-73 (Fed. Cir. 2005). "Enablement is a question of law based on underlying factual findings." *MagSil Corp. v. Hitachi Global Storage Technologies, Inc.*, 687 F.3d 1377, 1380 (Fed. Cir. 2012). Summary judgment is appropriate if the undisputed factual evidence establishes that the patent specification fails to teach a person of ordinary skill how to make and use the claimed invention. *Streck, Inc. v. Research & Diagnostic Systems, Inc.*, 665 F.3d 1269, 1288 (Fed. Cir. 2012).

Method of nucleic acid sequence analysis. Promega argues that the specification shows that at the time of the patent application Life Tech did not possess, and therefore may not claim, a "method of nucleic acid sequence analysis" other than the Sanger method of DNA sequencing. Because I have construed claim 62 to reach other methods, such as multiplex STR analysis, that the inventors of the '096 patent did not invent and did not possess, Promega argues that this claim is invalid.

Claim 62, remember, describes:

> 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.

My *Markman* order of April 4 held that as a matter of claim construction the preamble to this claim—"a method of nucleic acid sequence analysis"—does not limit the claim to DNA sequencing (determining the identity and order of each and every nucleotide in a DNA sequence). The claim reaches "any method of obtaining information

about a genetic sequence." But I did not address whether the claim, so construed, is adequately supported by the patent's specification.

The specification must "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc), quoting *Vas–Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562–63 (Fed. Cir. 1991). "The purpose of the written description requirement is to ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification…. It is part of the *quid pro quo* of the patent grant and ensures that the public receives a meaningful disclosure in exchange for being excluded from practicing an invention for a period of time." *Id.* at 1353–54 (quotation marks omitted). The inventor of one species may not claim the genus and thereby block the public from using other species, species that he has not discovered but that belong to the genus to which the species he has discovered belongs. See *id.* at 1349–50; *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1255 (Fed. Cir. 2004).

In *Chiron*, for example, a patent claimed "monoclonal antibodies" with certain properties. The specification in the earliest application for the patent showed that inventors knew how to make only one of the three types of monoclonal antibodies known to science (murine antibodies), and not the other two (chimeric and humanized antibodies). The district court construed the claim for monoclonal antibodies to reach all three types. The Federal Circuit upheld the construction, but held that the specification was inadequate to support a claim for the entire genus of monoclonal antibodies. Similarly, claim 62 of the '096 patent claims all methods of nucleic acid sequence analysis, but the patent specification describes only one such method (the Sanger method).

Life Tech points out that a patent's specification need not describe every possible use of the claimed invention. A patent covering a painkiller, for example, would not be invalid simply because it was later discovered to be effective against heart disease. Had the '096 patent claimed only a method of extending a fluorescently labeled oligonucleotide along a complementary strand of DNA, it would be no defense that Promega wanted to use that method to perform multiplex STR analysis instead of DNA sequencing. But Promega's multiplex STR analysis is not a new use of the Sanger method; it is a different *method*, having different goals (DNA fingerprinting, rather than DNA sequencing) and different elements, such as polymerase chain reaction (PCR), which hadn't been invented in 1984 when the application for the '096 patent was first filed.

Claim 62 and its dependent claims are therefore invalid.

Specifically hybridized oligonucleotides. Promega argues also (but unavailingly, as I am about to show) that claims 62 and 66 are invalid because they claim a broader range of oligonucleotides than the specification enables. In order to enable, the patent's specification must provide enough detail so that one skilled in the art at the time of the applica-

tion could "make and use the invention without undue experimentation." *In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988). "Enablement serves the dual function in the patent system of ensuring adequate disclosure of the claimed invention and of preventing claims broader than the disclosed invention." *MagSil Corp. v. Hitachi Global Storage Technologies, Inc.*, *supra,* 687 F.3d at 1380–81.

Claims 62 and 66 each require an oligonucleotide to be specifically hybridized to a complementary strand of DNA. Promega points out that making a specifically hybridized oligonucleotide requires knowing the sequence of nucleotide bases in the complementary strand to which it will bind. In DNA sequencing applications the sequence of the target strand is unknown, so it is impossible to create an oligonucleotide specifically hybridized to the target strand. Instead, a known strand (called, as noted earlier, a cloning vector) is attached to the start of the target strand, and an oligonucleotide designed to bind to the cloning vector is attached to start the process of replicating the target strand. The '096 specification discloses the use of an oligonucleotide specifically hybridized to a cloning vector known as M13.

Some more recent methods of analyzing a strand's nucleic acid sequence—including multiplex STR analysis—use an oligonucleotide designed to bind directly to a known portion of the target strand. But when the '096 patent application was first filed the Human Genome Project was not yet underway, and so it would have been impossible to create an oligonucleotide designed to bind to most locations on the human genome, including the locations to which Promega's oligonucleotides bind in multiplex STR analysis. Therefore, says Promega, the inventors did not enable "the full scope of the claimed invention." *Magsil Corp. v. Hitachi Global Storage Technologies, Inc.*, *supra*, 687 F.3d at 1380.

Life Tech's expert Dr. Norman Dovichi counters that designing an oligonucleotide to bind to a *known* DNA sequence would have been relatively easy in 1984 and could have been accomplished by one skilled in the art without undue experimentation. Promega's summary judgment motion offers no expert testimony contradicting this conclusion. The invention is thus enabled for all known DNA sequences. That is enough. "The law does not expect an applicant to disclose knowledge invented or developed after the filing date." *Chiron Corp. v. Genentech, Inc.*, *supra*, 363 F.3d at 1254. As the Human Genome Project sequenced new regions of human DNA, one skilled in the art could design oligonucleotides to bind to those regions without undue experimentation, thus enabling new uses of the claimed invention. But the inventors of the '096 patent were not required to identify in advance all of the DNA sequences that their claimed oligonucleotides could bind to.

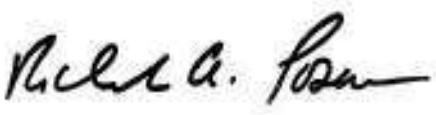
Promega argues that the written description requirement could not be satisfied unless the '096 specification recited the nucleotide sequence of every oligonucleotide within the scope of claims 62 and 66. The cases it cites, *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), and *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323

F.3d 956 (Fed. Cir. 2002), do not require this. Both cases involved claims to specific genes or DNA sequences—genes encoding insulin in *Eli Lilly*, and nucleic acid probes with sequences found in specific bacteria in *Enzo*. The '096 patent claims, in contrast, involve oligonucleotides that can be designed to bind to a wide variety of known DNA sequences. The '096 patent's specification describes one working example (the oligonucleotide specifically hybridized to the M13 cloning vector). It would be impractical to require more, and unnecessary because, as Dr. Dovichi explains, designing oligonucleotides to hybridize to additional locations would not require undue experimentation (if it did, this would imply that the disclosures in the patent itself were insufficient to enable a reader to create the patented invention) once the sequence of the target location was known.

In sum, the '096 patent's specifications adequately describe and enable the specifically hybridized oligonucleotides recited by claims 62 and 66.

Conclusion

All the claims of the '096 patent asserted by Life Tech are invalid, whether Smith '800 is considered prior art or not. Claim 62 and its dependent claims are invalid because failing to meet the written description requirement, because anticipated by the '800 patent and as double patenting. Claim 66 fails because anticipated by the '800 patent and as double-patenting. And claim 67 is invalid as obvious in light of the Ruth '882 patent and the reference in the research abstract that I mentioned.



United States Circuit Judge

June 12, 2013