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Hour 1—Recent Developments in Chemical, Pharma and Bio Patents (January 17, 2017)

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METHOD OF DETECTING AN ALLELE USING “JUNK DNA” IS PATENT INELIGIBLE

By Shawn Hamidinia, Ph.D.
Birch, Stewart, Kolasch & Birch, LLP
January 17, 2017


INTRODUCTION

At issue in Genetic Technologies Limited v. Merial L.L.C., Bristol-Myers Squibb Co. was whether a claim related to a method for detecting an allele by amplifying and analyzing non-coding regions known to be linked to the coding region was patent eligible subject matter under 35 U.S.C. § 101.

FACTS

Genetic Technologies owns the ’179 patent. Claim 1 at issue in the ’179 patent reads as follows:

1. A method for detection of at least one coding region allele of a multi-allelic genetic locus comprising:
   a) amplifying genomic DNA with a primer pair that spans a non-coding region sequence, said primer pair defining a DNA sequence which is in genetic linkage with said genetic locus and contains a sufficient number of non-coding region sequence nucleotides to produce an amplified DNA sequence characteristic of said allele; and
   b) analyzing the amplified DNA sequence to detect the allele.

The inventor of the ’179 patent was the first to discover that alleles of a particular gene may be detected by amplifying and analyzing non-coding regions (introns) in linkage disequilibrium with the coding region (exons). At the time of the invention, non-coding regions of DNA were referred to as “junk DNA” because, at that time, they appeared to serve no function. The method of the ’179 patent possessed several advantages over prior art methods involving direct analysis of a coding region, including analysis of short regions of non-coding sequences which can be amplified compared to prior art analyses such as cDNA RFLP analyses which involve the use of significantly larger DNA sequences. Applications of the method
of the ’179 patent include diagnosis and treatment of genetic disorders correlated with specific alleles (e.g., sickle-cell anemia, hemophilia, and cystic fibrosis).

**DISCUSSION OF THE CASE**

Genetic Technologies appealed the district court’s decision finding that Merial L.L.C and Bristol-Myers Squibb did not infringe U.S. Patent No. 5,612,179 (“the ’179 patent) because the claims were invalid under 35 U.S.C. § 101. The Federal Circuit affirmed the district court’s grant to dismiss under Rule 12(b)(6) in favor of Merial L.L.C. and Bristol-Myers Squibb ruling that claim 1 of the ’179 patent was invalid for claiming patent ineligible subject matter.

Beginning with step one of the well-established Mayo/Alice two-step test for patent eligibility, the Federal Circuit ruled that claim 1 is directed to a relationship between non-coding and coding sequences and the tendency of non-coding sequences to be representative of the linked coding sequences, which is a law of nature. The Federal Circuit found that claim 1 broadly covers essentially all applications of the law of linkage disequilibrium to the problem of detecting coding sequences of DNA.

Proceeding with step two of the Mayo/Alice analysis, the Federal Circuit found that the steps of “amplifying genomic DNA with a primer pair” and “analyzing the amplified DNA sequence to detect the allele” were “well known, routine and conventional” in the field of molecular biology at the time of filing the application. Thus, the court concluded that claim 1 did not include additional elements sufficient to amount to “significantly more” than the law of nature.

In responding to Genetics Technologies argument that “no one had before analyzed man-made non-coding DNA in order to detect a coding region allele,” the Federal Circuit reasoned that the phrase “to detect the allele” is a mental process step because it sets forth a routine comparison that can be performed by the human mind. The Federal Circuit explained that the limitation “to detect the allele” merely asks the user to compare the non-coding sequence amplified and analyzed with a library of non-coding sequences known to be in linkage disequilibrium with certain coding region alleles.

Similar to the court’s decision in Ariosa v. Sequenom, the Federal Circuit held that even valuable contributions can fall short of statutory patentable subject matter.
PRACTICE TIPS

When drafting or amending claims directed to a judicial exception, it is important to consider whether a non-obvious and unconventional element can be added to satisfy step two of the *Mayo/Alice* two-step test for patent eligibility.

Importantly, when a practitioner is concerned about a particular application being patent ineligible, they must convey those concerns clearly to the inventor. This is best done during drafting, but certainly as soon as discovered.
CLAIM INTERPRETATION AND ITS EFFECTS ON INFRINGEMENT AND VALIDITY AT TRIAL

By John Heithaus
Birch, Stewart, Kolasch & Birch, LLP
January 17, 2017

Lifenet Health v. Lifecell Corporation, 837 F.3d 1316 (Fed. Cir. 2016)

INTRODUCTION

The Federal Circuit reviewed a decision from the E.D. of Virginia that claims of U.S. Patent No. 6,569,200 (the ’200 patent) of Lifenet were infringed by Lifecell. The Federal Circuit upheld the decision of the district court holding that 1) Lifecell did not adequately present the claim construction argument raised on appeal and thus the issue could not be considered, 2) the non-removal limitation “said one or more plasticizers are removed from said internal matrix…prior to transplantation” is a functional limitation and does not require actual activity thus direct infringement is present, 3) as the non-removal limitation defines a property of the plasticizer the claim is properly in a single statutory class, 4) the construction of “plasticized skin graft” to not require “dehydrated” was proper because the ’200 patent only used the word dehydrated broadly and there was no support that the claimed soft tissue was dehydrated to a certain degree, and 5) substantial evidence supports the finding that Werner did not anticipate the ’200 patent because Dr. Kaplan maintained that the difference in mechanical properties was sufficient to meet the court’s construction of “plasticized soft tissue graft.”

FACTS

Lifenet’s ’200 patent concerns soft tissue grafts which are plasticized and thereby avoid the problems of freeze drying associated with prior art methods. Claim 1 of the ’200 patent recited:

A plasticized soft tissue graft suitable for transplantation into a human, comprising:

a cleaned soft tissue graft having an internal matrix; and

one or more plasticizers contained in said internal matrix;

said one or more plasticizers are not removed from said internal matrix of said plasticized soft tissue graft prior to transplantation into a human.
Lifecell’s accused products were soft tissue grafts preserved in plasticizer, but Lifecell instructed users to soak the tissue grafts in saline solution for a minimum of two minutes prior to implementation. Lifecell’s saline treatment removed a significant amount of plasticizer from the soft tissue. However, the saline treatment did not remove plasticizer from the internal matrix of the soft tissue.

The prior art Werner disclosed a process for treating soft tissue with hydrogen peroxide and other steps to increase biological stability.

**DISCUSSION OF THE CASE**

1) Lifecell argued that the district court erred by allowing the jury to resolve the dispute about the scope of the limitation “said one or more plasticizers are not removed from internal matrix of plasticized soft tissue graft”. The district court found that the limitation required no construction. Specifically, at the *Markman* stage the court found the two-word phrase “not removed” meant that no plasticizer was removed. The court did not go on to discuss *from where* those plasticizers were removed. Lifecell did not dispute at the *Markman* stage that the non-removal was directed to “the internal matrix of the … tissue graft.” Lifecell implored the Federal Circuit to adopt the construction that the claim should have been interpreted such that the internal matrix and soft tissue graft are one and the same.

The court found that Lifecell did not timely request modification of the claim construction. It is incumbent that the appellant raised the claim construction argument before the district court, and, having failed to do so cannot resurrect the argument on appeal by pointing to ambiguous statements of record.

2) Lifecell argued that the non-removal limitation “said one or more plasticizers are removed from said internal matrix…prior to transplantation” precludes direct infringement of the claim by Lifecell. Direct infringement requires each and every limitation appear in the accused product. Lifecell argued that the non-removal limitation could not be met until a third party actually prepares and uses the accused product. The court disagreed. The Federal Circuit found that functional limitations recited in the negative can describe capability and structural elements. Thus, the non-removal limitation did not relieve Lifecell of direct infringement.

3) Lifecell argued that the non-removal limitation described a method of use while the remainder for the claim described an apparatus, and
thus, the claim was indefinite for improperly covering two statutory classes. The court disagreed. The Federal Circuit noted again that functional claiming is acceptable. The non-removal limitation defined a property of the recited plasticizer.

4) Lifecell contended that the district court erred in its construction of plasticized soft tissue graft. The district court construed the limitation to require “free and loosely bound waters of hydration in the tissues have been replaced with one or more plasticizers.” Lifecell contended that that the tissue graft needed to be dehydrated, i.e. only have low residual moisture. The court found that the ’200 patent specification only used the word dehydrated broadly. The court found no support for the proposition that the claimed soft tissue graft must be dehydrated or completely desiccated. The court declined to adopt Lifecell’s proposed construction.

5) Lifecell argued that the claims were anticipated and/or obvious in view of Werner. Lifenet disputed that Werner met the two limitations “cleaned” and “plasticized soft tissue graft”. The district court found that the limitation “plasticized soft tissue graft” to require “without altering the orientation of the collagen fibers, such that the mechanical properties, including the material, physical and use properties, of the tissue are similar to those of normal hydrated tissue.” The Federal Circuit noted that the record showed that the expert explained that in Werner the mechanical properties were significantly altered from native tissue. The expert concluded that the difference in Werner was significant enough not to meet the courts construction of plasticized soft tissue graft. Thus, the decision of the district court was again affirmed.

PRACTICE TIPS

If challenging claim construction do so early and frequently. It is acceptable to use functional limitations in an apparatus claim. Do not indicate in a specification that a property is required. Claim construction can significantly affect later efficacy of anticipation/obviousness arguments.
INTRODUCTION

The Medicines Company v. Hospira, Inc. (MedCo) v. Hospira, Inc. arose from two Abbreviated New Drug Applications (ANDAs) filed by Hospira against two U.S. Patents held by MedCo. The U.S. Patents relate to the drug bivalirudin, marketed as Angiomax in the U.S. Among other issues, in MedCo, the Federal Circuit, sitting en banc, overturned an earlier Federal Circuit panel decision and affirmed the District Court’s holding that there was no invalidating on-sale bar under 35 U.S.C. § 102(b). In short, the Federal Circuit held that as a general proposition, it looks to the Uniform Commercial Code (UCC) to determine whether the facts at issue are sufficient to rise to the level of a commercial offer for sale.

The Federal Circuit held that a contract manufacturer’s sale of manufacturing services to the inventor where neither title to the embodiments nor the right to market the same passes to the supplier does not constitute an invalidating sale under § 102(b).

The Court did not reach other issues raised on appeal, including whether the invention was ready for patenting at the time of the relevant transactions, whether the Distribution Agreement between MedCo and ICS triggered the on-sale bar, or the merits of either MedCo’s appeal of the district court’s claim construction and non-infringement rulings or Hospira’s cross-appeal of the district court’s obviousness and indefiniteness rulings. These issues were remanded to the original Fed. Cir. panel for further proceedings.

The issue addressed herein relates to specific facts surrounding the contract manufacturing of bivalirudin by a third party for MedCo, and why such facts were insufficient to give rise to an on-sale bar.

FACTS

MedCo owns U.S. Patent Nos. 7,582,727 (“the ’727 patent”) and 7,598,343 (“the ’343 patent”) directed to a form of bivalirudin. Both patents are listed
in the FDA’s Orange Book as covering Angiomax, the trade name of a bivalirudin formulation that MedCo markets in the United States. Two ANDAs were filed by Hospira seeking FDA approval to sell generic bivalirudin before the expiration of the ’727 and the ’343 patents.

Bivalirudin is a synthetic peptide comprised of twenty amino acid residues that is used as an anticoagulant:

![Chemical structure of bivalirudin](image)

**bivalirudin**

The ’727 and the ’343 patents claim pH-adjusted pharmaceutical batches of bivalirudin and a pharmaceutically acceptable carrier. The bivalirudin active pharmaceutical ingredient, without further processing, is too acidic for human injection, therefore, MedCo prepares Angiomax using a compounding process in which it creates a bivalirudin solution, adjusts the solution’s pH with a base, and then freeze-dries the solution. A potential adverse consequence of this compounding process is degradation of bivalirudin, which may form impurities such as Asp⁹-bivalirudin (“Asp⁹”). The bivalirudin may become unusable if high levels of Asp⁹ form.

In 1997, MedCo contracted with Ben Venue Laboratories (“Ben Venue”), a third-party provider, for manufacture of commercial quantities of an original formula of Angiomax not covered under the patents-in-suit. In June 2005, Ben Venue manufactured a batch of bivalirudin drug product with an Asp⁹ level of 3.6% (which exceeded the FDA’s approved maximum level of 1.5%). MedCo discarded that batch and shut down production of Angiomax for six months to investigate the problem and revise its process. In 2006, another batch had an unacceptable Asp⁹ level, so MedCo again shut down production of Angiomax and hired a specialist to investigate and resolve the issue.

The investigation led to the development of the new compounding process claimed in the patents-in-suit. Ben Venue has made all
batches since October 2006 using the new process. According to MedCo, the process produces an improved Angiomax product with a maximum Asp⁹ level of 0.6%. The '727 and '343 patents contain product and product-by-process claims, respectively, for pharmaceutical batches of the improved drug product with a maximum impurity level of Asp⁹ of 0.6%.

**Claim 1 of the '727 patent is as follows:**

1. Pharmaceutical batches of a drug product comprising bivalirudin (SEQ ID NO: 1) and a pharmaceutically acceptable carrier for use as an anticoagulant in a subject in need thereof, wherein the batches have a pH adjusted by a base, said pH is about 5-6 when reconstituted in an aqueous solution for injection, and wherein the batches have a maximum impurity level of Asp⁹-bivalirudin that does not exceed about 0.6% as measured by HPLC.

**Claim 1 of the '343 patent is as follows:**

1. Pharmaceutical batches of a drug product comprising bivalirudin (SEQ ID NO: 1) and a pharmaceutically acceptable carrier, for use as an anticoagulant in a subject in need thereof, said batches prepared by a compounding process comprising:
   
   (i) dissolving bivalirudin in a solvent to form a first solution;
   
   (ii) efficiently mixing a pH-adjusting solution with the first solution to form a second solution, wherein the pH-adjusting solution comprises a pH-adjusting solution solvent; and
   
   (iii) removing the solvent and pH-adjusting solution solvent from the second solution;

   wherein the batches have a pH adjusted by a base, said pH is about 5-6 when reconstituted in an aqueous solution for injection, and wherein the batches have a maximum impurity level of Asp⁹-bivalirudin that does not exceed about 0.6% as measured by HPLC.

The applications for the '727 and '343 patents were filed on July 27, 2008. The critical date from which the on-sale bar of § 102(b) must be measured is, therefore, July 27, 2007. In late 2006, MedCo paid
Ben Venue to manufacture three batches of bivalirudin according to the patents-at-issue. Ben Venue completed the first such batch on October 31, 2006, the second batch on November 21, and the third batch on December 14, 2006. According to Hospira, the three batches had a market value of well over $20 million. Once manufactured by Ben Venue, the three batches were placed in quarantine with MedCo’s distributor, Integrated Commercialization Solutions (“ICS”), pending FDA approval.

MedCo and ICS entered into a Distribution Agreement effective February 27, 2007. The Distribution Agreement made ICS the exclusive authorized distributor of Angiomax in the U.S. and stated that title and risk of loss would pass to ICS following release from quarantine. Under the Distribution Agreement, ICS would place individual purchase orders with MedCo on a weekly basis, which MedCo could accept or reject. It was not until August 2007 (after the July 27, 2007 critical date) that MedCo released the three batches from quarantine and made them available for sale.

On August 19, 2010, MedCo sued Hospira in the District Court for the District of Delaware, alleging that Hospira’s two ANDA filings infringed the ’727 and the ’343 patent. Hospira counterclaimed alleging, among other things, that MedCo’s patents were invalid due to an on-sale bar.

The District Court found, *inter alia*, that there was no on-sale bar based upon the activities of MedCo.

**Discussion of the Case**

A merits panel disagreed with the District Court\(^1\), explaining that, “where the evidence clearly demonstrated that the inventor *commercially exploited* the invention before the critical date, even if the inventor did not transfer title to the commercial embodiment of the invention,” the on-sale bar applies. MedCo petitioned for panel rehearing or rehearing *en banc*, and on November 13, 2015, The Federal Circuit granted rehearing *en banc*, vacated the panel’s decision, reinstated the appeal, and ordered new briefing on issues including whether the circumstances constitute a commercial sale under the on-sale bar of 35 U.S.C. § 102(b).

The Federal Circuit found that the transactions between MedCo and Ben Venue did not constitute commercial sales of the patented product, rationalizing that when assessing the on-sale aspect of

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\(^1\) MedCo., 791 F.3d 1368 (Fed. Cir. 2015).
§ 102(b), the court must focus on those activities that would be understood to be commercial sales and offers for sale “in the commercial community.” The Court also stressed that “[a]s a general proposition, we will look to the Uniform Commercial Code (‘UCC’) to define whether . . . a communication or series of communications rises to the level of a commercial offer for sale.”

The Court explained that (1) the mere sale of manufacturing services by a contract manufacturer to an inventor to create embodiments of a patented product for the inventor does not constitute a “commercial sale” of the invention; (2) with regard to the issue of “stockpiling” by an inventor, it clarified that “stockpiling” by the purchaser of manufacturing services is not improper commercialization under § 102(b); and (3) commercial benefit—even to both parties in a transaction—is not enough to trigger the on sale bar of § 102(b). Rather, the transaction must be one in which the product is “on sale” in the sense that it is “commercially marketed.”

In reaching these decisions, the Federal Circuit explained that three main reasons were key: (1) only manufacturing services were sold to the inventor—the invention was not; (2) the inventor maintained control of the invention, as shown by the retention of title to the embodiments and the absence of any authorization to Ben Venue to sell the product to others; and (3) “stockpiling,” standing alone, does not trigger the on-sale bar.

PRACTICE TIPS

When assessing a potential on-sale issue, it is important to consider the activities at issue would be understood to be commercial sales and offers for sale “in the commercial community.” Particular attention should be given to the Uniform Commercial Code (‘UCC’) to define whether transaction or communications rise to the level of a commercial sale or offer for sale, respectively.
UNITED WE STAND, DIVIDED WE FALL – OR UNITED WE INFRINGE, DIVIDED WE DON’T

Craig McRobbie
Birch, Stewart, Kolasch & Birch, LLP
January 17, 2017


INTRODUCTION

In Medgraph, Federal Circuit affirmed the District Court decision granting summary judgement of no infringement, applying the law as stated in the final en banc Federal Circuit Akamai decision² (named Akamai V). In Akamai V, the Federal Circuit held that for purposes of divided infringement, in addition to an agency or contractual relationship, attribution is proper “when an alleged infringer conditions participation in an activity or receipt of a benefit upon performance of a step or steps of a patented method and establishes the manner or timing of that performance.”³ The Federal Circuit explained that “[s]tated otherwise, an actor who is implicated in that way in all of the claimed steps it does not itself perform may be liable as a direct infringer.”⁴

Applying the holding in Akamai V to the facts of Medgraph, the Federal Circuit found that Medgraph has not pointed to any evidence that would permit attribution of patient- and doctor-performed steps to Medtronic under the sole standard of Akamai V. Therefore, the Federal Circuit affirmed the holding of the District Court granting summary judgement of no infringement.

FACTS

Medgraph owns by assignment U.S. Patent 5,974,124 (“the ’124 patent”) and U.S. Patent 6,122,351 (“the ’351 patent”). The patents are generally directed to a method (and system) for improving and facilitating diagnosis and treatment of patients, whereby data relating to “medically important variable[s],” for example, blood sugar levels of a diabetic patient, measured

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3. Akamai V, 797 F.3d at 1023.
from a patient’s body, are uploaded onto a computer and transmitted to a central storage device, from which they can be accessed remotely by medical professionals treating the patient.

Claims 1–15 of the '124 patent are method claims. Claim 1 is representative and reads as follows:

1. A method for improving and facilitating diagnosis and treatment of patients having medical conditions requiring long-term profiles of specific variables, said method including the steps of

   using at least one measuring device, periodically taking a measurement of at least one medically important variable that has been identified for a patient from a body of said patient;

   ensuring said patient is separated from said at least one measuring device after taking each said measurement;

   inputting said at least one medically important variable as raw data into a primary computer system after said step of ensuring said patient is separated and recording said raw data in a mass storage device integrated with said primary computer system;

   compiling said raw data as data for said patient using the primary computer system, said data representing a history of values for said at least one medically important variable for said patient;

   receiving a request for data of one of said patients from by a medical practitioner that is treating said one of said patients; and

   outputting requested data for said one of said patients in the form of at least one of a chart and a graph to said medical practitioner;

said step of inputting comprising one of

   transferring said raw data to a remote computer comprising an ordinary general purpose personal computer, then transferring said raw data to said primary computer;

   telephoning an automatic telephone interface and employing one of speech recognition and touch-tone recognition software to input said raw data into said primary computer; and

   telephoning a live receptionist, speaking the raw data to said live receptionist for entry into said primary computer.
The ’351 patent, which is a continuation-in-part of the ’124 patent, sets forth a single, similar claim, with differences that are not relevant to this particular appeal. Claim 16 of the ’124 patent is the corresponding system claim, and reads in relevant part:

16. A system for improving and facilitating diagnosis and treatment of patients having medical conditions requiring long-term profiles of at least one prede
termed medically important variable, comprising . . .

means for inputting said at least one predetermined medically important variable as raw data into a primary computer comprising software and hardware enabling said primary computer system to operate as at least one of a web server, a dial-up host, a network server, and a telephone answering and data collection device whereby raw data can be communicated from a remote computer proximate a patient comprising an ordinary general purpose personal computer and from an ordinary telephone wherein data is transmitted as one of spoken data and touch-tone data; . . .

means to transmit said requested data in the form of at least one of a chart and graph generated from said data from said primary computer to a remote computer proximate said practitioner whereby said primary computer is one of a web server, a dial-up host, and a network server and means to transmit said requested data by facsimile through a faxmodem integrated with said primary computer . . . .

Medtronic manufactures and markets a variety of integrated diabetes management solutions, including the CareLink® Therapy Management System for Diabetes, which integrates CareLink Personal Therapy Management Software (“CareLink Personal”) for patients and CareLink Pro Diabetes Therapy Management Software (“CareLink Pro”) for healthcare professionals (collectively, the “CareLink System”).

The CareLink System allows patients to upload data relating to management of their diabetes, including blood glucose readings, to Medtronic’s central computer server, where the data are collected and stored in a database so that the patients can keep an online record of the information, and/or share the information remotely with a healthcare provider.

Medgraph sued Medtronic over the CareLink System.

**DISCUSSION OF THE CASE**

In a somewhat “up and down” process involving different versions of the Akamai case, the United States District Court for the Western District of New York ultimately issued a decision granting summary judgment of no infringement, applying the law on direct infringement liability as it then stood (Akamai IV). The District Court found that there was no infringement because there had not been any “showing that Medtronic itself directly infringed the method claims or that it acted as a ‘mastermind’ by
controlling or directing anyone else’s direct infringement.” Shortly thereafter, the Akamai V decision was issued by the Federal Circuit and Medgraph appealed to the Federal Circuit.

Under Akamai V, the Federal Circuit had found that Limelight “conditions customers’ use of its content delivery network” upon its customers performing the certain claimed steps of “tagging” and “serving.” Evidence supporting this conclusion was, first, a requirement in Limelight’s standard contract that its customers perform the tagging and serving steps if they want to use Limelight’s service. Second, Limelight’s welcoming letter telling customers that a Limelight Technical Account Manager will lead implementation of Limelight’s services and providing “step-by-step instructions” that customer must follow with respect to the “tagging” and “serving.” Accordingly, the Federal Circuit held Limelight liable for direct infringement because “all steps of the claimed methods were performed by or attributable to Limelight.”

In Medgraph, the Federal Circuit did not find facts sufficient to attribute the claimed method steps to Medtronic. The Federal Circuit found that Medgraph had not pointed to any evidence that would permit attribution of patient- and doctor-performed steps to Medtronic.5 The Court explained: “The evidence presented to the District Court indisputably shows that Medtronic does not condition the use of, or receipt of a benefit from, the CareLink System on the performance of all of Medgraph’s method steps. For example, Medtronic does not deny users the ability to use CareLink Personal and CareLink Pro without performance of the claim step of ensuring detachment of the measuring device from the patient after each measurement. Nor does it offer an incentive for such detachment. Indeed, the evidence indicates that Medtronic benefits when patients use its continuous glucose monitoring device, which does not involve ensuring detachment after each measurement.”6

The Federal Circuit also pointed out that the evidence further showed that Medtronic freely permits using the CareLink System without performing synchronization, and it denies no benefit to such users for their choices to do so. Patients can freely choose to bring their devices to their physician’s office and have their data extracted locally there. Patients also can print or email reports and bring them to their medical practitioner.

Thus, the Court found that the evidence was simply insufficient to meet the requirements of Akamai V. The Federal Circuit therefore affirmed the District Court holding of no infringement.

5. Medgraph, slip opinion at 9.
PRACTICE TIPS

When drafting claims, especially method claims involving personalized healthcare, take care to envision the ultimate scenario of infringement. Whenever possible, do not recite particular steps, if such steps are either unnecessary, or if such steps will be performed by an entity that is outside of the control of the main practicing entity.
HOW DEEP IS THE OCEAN, HOW HIGH IS THE SKY, HOW STRONG IS “CONSISTING OF” PRESCRIPTION? THE ANSWER, OF COURSE, IS THE SAME: IT DEPENDS

By Gleb Savych
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January 17, 2017

Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp., 831 F.3d 1350 (Fed. Cir. 2016)

INTRODUCTION

In Multilayer, the Federal Circuit applies and elaborates on the long standing presumption that the phrase “consisting of” preceding a list of elements in a claim signals that the list is exclusive. The Court concludes that presumption against inclusion of unlisted elements is strong and may be overcome only if an alternative meaning is unmistakably manifested in the specification or prosecution history. However, the presumption against inclusion of mixtures and blends of the listed elements is weaker and more easily overcome in the specification.

FACTS

Multilayer Stretch Cling Film Holdings, Inc. (“Multilayer”) sues Berry Plastics Corp. (“Berry”), for infringing its patent directed to multilayered plastic cling films. Berry argued that its films did not infringe under proper claim construction and counterclaimed invalidity.

Independent claim 1 of Multilayer patent recites in pertinent part:

1. A multi-layer, thermoplastic stretch wrap film containing seven separately identifiable polymeric layers, comprising:
   a) two identifiable outer layers . . . ; and
   b) five identifiable inner layers, with each layer being selected from the group consisting of linear low density polyethylene [LLDPE], very low density polyethylene [VLDPE], ultra low density polyethylene [ULDPE], and metallocene-catalyzed linear low density polyethylene resins [mLLDPE] . . . .

The District Court construed element (b) to mean that each of the five inner layers must contain only one of the listed four classes of resins and cannot contain any blends. The District Court also construed LLDPE
broadly as encompassing the other three listed resin classes. The District Court concluded that a layer containing a mLLDPE resin and another LLDPE resin that was not mLLDPE would constitute an impermissible blend and thus fall outside of the claim scope.

Dependent claim 10 further requires that at least one of the inner layers of claim 1 is comprised of low density polyethylene (LDPE). The District Court construed the term LDPE as having a branched polymer backbone (unlike the LLDPE) and held that claim 10 was invalid because it impermissibly enlarged the scope of claim 1 since LDPE was not one of the elements of claim 1.

Because the accused products had layers containing other resins as well as blends of resins listed in claim 1, the District Court granted summary judgement of noninfringement.

DISCUSSION OF THE CASE

The Federal Circuit reversed one aspect of the District Court’s claim construction and remanded for determination of infringement consistent with its new claim construction.

The Court observed that element (b) of claim 1 is written as a Markush claim listing alternative species that can be selected as part of the claimed element. The court identified two issues of claim construction: 1) whether the Markush group is closed to resins other than the listed four; and 2) whether it is closed to blends of the four listed resins.

The Court noted that the phrase “consisting of” is a term of art that creates a strong presumption that the group is closed to unlisted elements. The court emphasized that this construction has been affirmed by courts many times over its century-long history. The Court stated that a patentee could overcome this presumption by becoming its own lexicographer and giving “consisting of” an alternative meaning, which must be unmistakably manifested in the specification or prosecution history. The Court found no such manifestation in this case.

Multilayer specifically focused its arguments on LDPE (recited in claim 10). It conceded that LDPE was not encompassed by any of the listed resins but argued that the specification made it clear that LDPE was suitable for inner layers of their film, thus rebutting the presumption that the Markush group was closed. However, the Federal Circuit concluded that any statements to that effect in the specification were not sufficient to overcome the strong presumption.

Multilayer further argued that because dependent claim 10 recites LDPE as a further limitation of claim 1, it was clear that claim 1 was meant
to encompass LDPE. Multilayer urged that claims should be construed so as to not render dependent claims meaningless. The Federal Circuit disagreed, stating that dependent claims cannot change the scope of an independent claim whose meaning is clear on its face.

Separately, the Federal Circuit found that the Markush group of claim 1 was open to blends of the listed resins, stating that a layer could still “consist of” the listed resins if it consisted of a mixture of those resins. Citing *Abbot*, the Court acknowledged that the use of “consisting of” creates a presumption against mixtures but found that this presumption was not as strong as presumption against inclusion of unlisted elements. The Court found that repeated references to mixtures throughout the specification and the fact that the term LLDPE encompassed at least mLLDPE, indicating overlap between the listed classes of resins, were sufficient to overcome this presumption.

Finally, because the Markush group was closed and LDPE was not encompassed by any of the listed resins, the Court affirmed the invalidity of dependent claim 10 as impermissibly enlarging the scope of independent claim 1.

**PRACTICE TIPS**

The phrase “consisting of” preceding a Markush group creates a strong presumption that the group is closed to unlisted elements. This presumption may be overcome only by an unmistakable manifestation of the alternative meaning in the specification or prosecution history. The language “consisting of” also creates a presumption against inclusion of mixtures and blends of Markush group elements, but this presumption is weaker.

When you use “consisting of” in a Markush language format, only do so if you are choosing to close the group to additional ingredients. If you do not want to “close” the group, then question why you are attempting to use Markush language in the first place.

Also, if you intend for “blends” to be encompassed by your Markush language, then specifically recite blends (e.g., one or more resin selected from the group consisting of…). Of course, ensure that you have suitable written description for such scope.

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7. 334 F.3d at 1281.
APPLICATIONS OF A NATURAL DISCOVERY MAY BE PATENT ELIGIBLE

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*Rapid Litigation Management Ltd. v. CellzDirect, Inc.*, No. 2015-1570
(Fed. Cir. July 5, 2016)

INTRODUCTION

Rapid Litigation Management appealed the summary judgment determination of the District Court for the Northern District of Illinois that U.S. Patent No. 7,604,929 (“the ’929 Patent”) is invalid under 35 U.S.C. § 101. The district court concluded that the ’929 Patent is directed to a patent-ineligible law of nature (i.e., that hepatocytes are capable of surviving multiple freeze-thaw cycles) and that the patented process lacks the requisite inventive concept. The Federal Circuit held that the claims of the ’929 Patent are not directed to a patent-ineligible concept, so the district court’s decision was vacated and remanded.

Note: In an *Ex Parte* Reexamination Certificate issued on February 28, 2012, the patentability of claims 1-9 and 11 was confirmed and claim 10 (independent) was cancelled.

FACTS

The ’929 patent is directed to an improved process comprising (A) subjecting previously frozen and thawed cells to density gradient fractionation to separate viable cells from non-viable ones; (B) recovering the viable cells; and (C) refreezing the viable cells.

Specifically, claim 1 recites:

1. A method of producing a desired preparation of multi-cryopreserved hepatocytes, said hepatocytes, being capable of being frozen and thawed at least two times, and in which greater than 70% of the hepatocytes of said preparation are viable after the final thaw, said method comprising:

   A. subjecting hepatocytes that have been frozen and thawed to density gradient fractionation to separate viable hepatocytes from non-viable hepatocytes,
B. recovering the separated viable hepatocytes, and
C. cryopreserving the recovered viable hepatocytes to thereby form said desired preparation of hepatocytes without requiring a density gradient step after thawing the hepatocytes for the second time, wherein the hepatocytes are not plated between the first and second cryopreservations, and wherein greater than 70% of the hepatocytes of said preparation are viable after the final thaw.

Rapid Litigation Management sued CellzDirect for infringing the ’929 Patent. In response, CellzDirect filed a motion for summary judgment of invalidity under 35 U.S.C. §§ 101 and 112. The district court granted the motion with respect to § 101 without reaching the § 112 issues. The district court applied the Supreme Court’s two-step framework for determining patent eligibility. At step one, the district court concluded that the ’929 Patent is directed to an ineligible law of nature. At step two, the district court determined that the patented process lacks the requisite inventive concept since the inventors reapplied a well-understood freezing process.

Rapid Litigation Management appealed the district court’s decision.

DISCUSSION OF THE CASE

Step one of the two-part test articulated by the Supreme Court for issues under 35 U.S.C. § 101 asks whether the claim is directed to one of the patent-ineligible concepts. If the answer is no, the claim recites patent-eligible subject matter. If the answer is yes, the test proceeds to step two, which asks whether the additional elements transform the nature of the claim into a patent-eligible application.

For step one, the district court concluded that the patent is directed to an ineligible law of nature with respect to the discovery that hepatocytes are capable of surviving multiple freeze-thaw cycles. The Federal Circuit disagreed with this conclusion. The Federal Circuit noted that the claims are not simply directed to the ability of hepatocytes to survive multiple freeze-thaw cycles. Rather, the claims are directed to a new and useful laboratory technique for preserving hepatocytes. Although the inventors discovered the cells’ ability to survive multiple freeze-thaw cycles, the inventors then applied their natural discovery to create a new and improved way of preserving hepatocyte cells for later use.

Although not necessary, the Federal Circuit then considered step two. The Federal Circuit determined that the claims of the ’929 Patent recite an improved process for preserving hepatocytes for later use, which is
sufficient to be considered a patent-eligible concept. Specifically, although the step of freezing and thawing hepatocytes was well-known, the Federal Circuit stated that the process of preserving hepatocytes by repeating the steps of freezing and thawing was far from routine and conventional.

Therefore, the Federal Circuit held that the claims of the '929 Patent are not directed to a patent-ineligible concept, so the district court’s decision was vacated and remanded.

**PRACTICE TIPS**

If the inventor makes a discovery of what is arguably a law of nature or other patent-ineligible subject matter, the inventor is still in a position to claim applications of that knowledge. Thus, inventors should consider how a natural discovery can be applied in new and improved ways in order to arrive at a patent-eligible invention. Similarly, patent practitioners drafting the patent specification must consider how a natural discovery can be applied in new and improved ways in order to draft patent-eligible claims.

Importantly, when a practitioner is concerned about a particular application being patent ineligible, they must convey those concerns clearly to the inventor.