THE CANCER LETTER

Vol. 39 No. 16
April 19, 2013



PO Box 9905 Washington DC 20016 Telephone 202-362-1809

*Reinventing Cancer Centers*

## Georgetown-Hackensack Consortium Plan Points to Rising Value of NCI Designation

*By Paul Goldberg*

Georgetown Lombardi Comprehensive Cancer Center and Hackensack University Medical Center John Theurer Cancer Center last week announced plans to affiliate, aiming to create a single consortium.

Located three states apart, the two institutions will start integrating their operations by building a bone marrow transplantation unit at Georgetown, where a BMT program was abandoned years ago.

"What we get out of it is an expanded capacity to conduct high-impact research," said Louis Weiner, director of Lombardi Cancer Center. "We will have additional colleagues, and we will have a much larger patient base on which to draw for our clinical trials."

(Continued to page 2)

*Patenting the Gene*

## In Myriad Case, the Supreme Court Hears About Tree Leaves, Baseball and Cookies

*By Matthew Bin Han Ong*

The Supreme Court earlier this week heard oral arguments in a landmark case involving two cancer-related genes.

The case, Association of Molecular Pathology vs. Myriad Genetics Inc., holds huge implications for all parties involved:

Myriad, the biotech company that has exclusive rights to the genes, would lose protection—and millions of dollars—if the court nullifies its patents. Moreover, other companies would be deterred from genetic research, some industry observers warn.

If the court upholds the patents, cancer and genomics researchers nationwide will continue to be barred from using the genes until the Myriad patents expire—for the next two years. And other genes will continue to be patented.

(Continued to page 4)

*In Brief*

## Alex Matter wins Szent-Györgyi Prize

**ALEX MATTER** was awarded the 8th **Szent-Györgyi Prize for Progress in Cancer Research** by the National Foundation for Cancer Research.

Matter played a role in the development of Gleevec, the first drug that specifically targets a molecular lesion in cancer.

(Continued to page 9)

## Consortium Plan Reminiscent Of Yale-Sarah Cannon Pact

(Continued from page 1)

"What they get out of it is an affiliation with an NCI-designated cancer center that we intend to grow and develop into a true consortium, as defined by the NCI Cancer Centers Program," Weiner said to The Cancer Letter.

An argument can be made that the Georgetown-Hackensack collaboration says something new about the value of the NCI comprehensive cancer center designation in the rapidly changing landscape of cancer research.

Cancer centers have been affiliating and creating consortia for decades, sometimes reaching across state lines. There is no doubt that the Georgetown-Hackensack consortium is reminiscent of several aspects of such collaborations. Yet, since no two cancer centers are exactly alike, no collaboration is completely duplicative.

The structure of this consortium is novel in part because of the distance between the two institutions, said Andrew Pecora, vice president for cancer services and chief innovations officer at Hackensack.

Distance is actually a plus, Pecora said to The Cancer Letter. "We are far apart," he said. "We see the advantage that we are not competing, which will allow for an even greater synergy."

In this case, the two high-quality centers are trying to advance their academic goals, enhance their prestige and compete more effectively in their cut-throat economic environments.

Hackensack has built a national reputation in hematologic malignancies, but was not the critical mass of basic and population research required for an NCI designation. Its goals in the collaboration include giving local residents an alternative to crossing the bridge to Manhattan to get care at an NCI-designated cancer center.

Georgetown, too, operates in a highly competitive environment. As a unit of the MedStar Health system, it's competing with another regional titan, the Johns Hopkins Health System, which is expanding its reach—and offering cancer services—in the Washington market.

Competition is so hot that at this writing, MedStar and Hopkins are clashing over plans to construct proton beam centers within a few blocks of each other.

While the need for proton beam centers anywhere is open to debate, the need for a transplant center in Washington may be more pressing. The Georgetown transplant unit stopped functioning around 2005. Now, a patient in need of a transplant has to go elsewhere, likely to Hopkins or the University of Maryland Greenebaum Cancer Center in Baltimore.

"Right now, there is not a fully academic, high-volume, high-impact transplant program in this region," Weiner said. "They are a minimum of an hour away without traffic from the DC region, and there are over five million people in our region. It's important to have services of that type available for the convenience of patients and their families."

Georgetown's revived transplant unit will be operated by Hackensack faculty, and the first autologous transplants would be offered in May.

**Hackensack: The Back Story**

Pecora, who was recruited to Hackensack from Memorial Sloan-Kettering Cancer Center in 1989, said one of his original goals was for the institution to pursue the NCI designation.

The Hackensack cancer center's primary area of emphasis is hematologic malignancies. Usually, Hackensack runs 100 clinical trials or more. Its bone marrow transplant program, which performs about 400 transplants a year, is one of the largest in the U.S. and the world.

"My goal was for us to get NCI-designated, and that was the goal of our institution," Pecora said. "We are clearly large enough and we do enough clinical research. We are bigger than the vast majority of NCI-designated cancer centers. We put more people on clinical trials.

THE CANCER LETTER

® The Cancer Letter is a registered trademark.

**Editor & Publisher**: Paul Goldberg
**Associate Editor**: Conor Hale
**Reporter**: Matthew Bin Han Ong

Editorial, Subscriptions and Customer Service:
202-362-1809 Fax: 202-379-1787
PO Box 9905, Washington DC 20016
General Information: www.cancerletter.com

Subscription $405 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc. 

We have as many clinical publications as many of them.

"Some of our investigators are lead investigators in national trials. Some of our investigators publish in Nature. We have that ilk of doc.

"We have R01 funded scientists, but we realized that the way our institution is configured, we would never have enough of the pure basic science and R01-funded researchers to get that accreditation."

As the Hackensack leadership looked at a variety of approaches, the consortium model seemed especially promising.

"We looked around the region to find the right partner, someone who wasn't directly in our catchment area, so we avoided the competition issue, but someone that we could work with and we liked and there were synergies," Pecora said.

The search for partners started around five years ago, and while a variety of centers were approached, before the prospect of forming a consortium with Georgetown, talks never advanced to the level of serious negotiations.

"It turned out that Lombardi is not that far from us—a couple-hour train ride—and yet close enough that we could do things together," Pecora said.

Weiner said the initial conversations that led to the collaboration were between senior officials at Georgetown University and Hackensack.

"They are very good in many areas, but they are especially good in cancer, and have been for quite some time," Weiner said. "As I saw it, this was not your conventional affiliation of a dominant academic cancer center with a community hospital.

"What we have here is an affiliation between an academic medical center that's home to a comprehensive cancer center, where the affiliation is with a very high-quality academically-oriented enterprise that probably would be challenged on its own to develop a comprehensive cancer center."

It will take several years for Georgetown and Hackensack to develop common programs and meet the NCI criteria for designation of a consortium, Weiner and Pecora said.

**Is NCI Designation Becoming a Portable Asset?**

Though NCI-designated cancer centers are a heterogeneous lot, the Georgetown-Hackensack union could suggest that the benefits of the NCI designation are becoming increasingly mobile.

While diversity of the centers mostly impedes analysis, the collaboration between the Yale Cancer Center and the Nashville-based Sarah Cannon Research Institute seems to be the closest parallel to the Georgetown-Hackensack consortium, Weiner said.

This is largely because in that collaboration, announced two years ago, Yale is working across state lines with the Nashville-based for-profit institution, Weiner said.

Thomas Lynch, director of Yale Cancer Center and physician-in-chief of the Smilow Cancer Hospital, concurred—sort of.

"The availability of electronic medical records, internet and videoconferencing have made the distances less of a concern," Lynch said to The Cancer Letter. "We've never looked at the geography. It's not going to hold them back."

Lynch is more than a disinterested observer of the Georgetown-Hackensack union. His late father, Thomas Lynch Sr., went into practice in a home-based office in Hackensack in 1962.

"He brought Andy [Pecora] over from Memorial," Lynch said. "The thing they have done so well is they have really focused on hematologic malignancies, and there is a lot of value in being focused. In myeloma and lymphoma and leukemia, they've really established themselves as one of the country's very best places. There is not a paper in myeloma that comes out without Hackensack being involved—same thing in lymphoma. Same thing in leukemia."

Though long distances are involved, the two collaborations aren't exactly analogous, Lynch said.

For one thing, Yale's collaboration with Sarah Cannon isn't intended to form a consortium cancer center.

Rather, it's illustrative of two even more interesting trends: the disappearance of boundaries that separate for-profit practices from non-profit institutions and, simultaneously, acquisition of physician practices by cancer centers, and, consequently, disappearance of the divide between community and academic oncology.

Yale's goal with Sarah Cannon is to affiliate in two areas: jointly conducting investigator-initiated trials at Yale and Sarah Cannon, and collaboration in industry-sponsored trials.

"Right now, American clinical cancer research is not competitive," Lynch said. "The time lines for opening trials and activating trials are unacceptable to industry. Sarah Cannon has the industry-best standards for doing industry trials."

In addition to these collaborations, Yale is drawing on Sarah Cannon's expertise in structuring working relationships with community physicians to involve them in clinical trials.

"We at Yale greatly increased our faculty through acquisition of former private practices," Lynch said. "You can't just acquire private practices. You have to find ways to make good clinical research happen through both the primary center and the practice site. And we are learning a ton from Sarah Cannon about how to work with physicians who practice predominantly in the community and really make that work."

Also, unlike Hackensack, Sarah Cannon doesn't conduct federally-funded research.

"I think they are spectacular," Lynch said. "If they wanted to be part of our NCI grant, I would certainly entertain it, but that hasn't been as necessary as wanting to do trials together."

Financial pressures, including sequestration, increase the need to think creatively, Lynch said.

"You have to figure out, like all industries do, how do you deal with the new reality?" he said. "The stakes are too high.

"You can't throw you hands up, run away and go home."

---

**Follow us on Twitter: @TheCancerLetter**

---

*Patenting the Gene*

## Search for Metaphor Dominates Oral Arguments in Myriad Case

(Continued from page 1)

In the hearing April 15, the justices drilled down into Myriad's patent rights to BRCA1 and BRCA2, the isolated genes which are associated with breast and ovarian cancer.

"If you cut off a piece of the whole in the kidney or liver, you're saying that's not patentable, but you take a gene and snip off a piece, that is?" Justice Sonia Sotomayor asked Myriad's attorney, Gregory Castanias, during the oral arguments.

"So what's the difference?"

The debate over patentability of the BRCA genes drew public attention when the Public Patent Foundation and American Civil Liberties Union—on behalf of several medical researchers, associations and patients—challenged Myriad's patent claims in 2009.

The plaintiffs prevailed at the Federal District Court in Manhattan.

However, the United States Court of Appeals for the Federal Circuit reversed the decision, leading the plaintiffs to petition the Supreme Court to reconsider several aspects of the ruling.

Nearly 60 "friend of the court" briefs were filed to the Supreme Court—research advocates and medical organizations largely sided with the petitioners. The American Medical Association, AARP and the National Women's Health Network are among the groups that filed briefs.

"Nobody 'invents' genes, so no one should be able to claim ownership of them," said Daniel Ravicher, executive director of the Public Patent Foundation. "We are not talking about a new drug or a new tool to fight cancer.

"We are talking about a genetic marker that occurs naturally in the human body," Ravicher said. "That cannot, and should not, be patented."

PhRMA and BIO, as well as individual drug and biotech companies filed briefs in support of Myriad. Prominent pro-Myriad parties include the Federal Circuit Bar Association, University of Baltimore/Johns Hopkins University Center for Medicine & Law, and the American Bar Association.

Arguably the highest-profile amicus brief was submitted by the Department of Justice, on behalf of the federal government's interests in support of neither party.

"The justices seem likely to rule in a way that tracks closely to the arguments of the U.S. government's top lawyer, the Solicitor General [Donald Verrilli], who had ten minutes to make his argument," said Robert Cook-Deegan, director of the Center for Genome Ethics, Law and Policy at the Duke University Institute for Genome Sciences and Policy.

Cook-Deegan's commentary on the oral arguments appears on page 7.

Present at the hearing were NIH Director Francis Collins and NCI Director Harold Varmus, who helped with the formulation of the DOJ amicus brief.

Earlier, Varmus said the case is of "immense concern to NCI."

"Francis and I and some others here at the NIH have been called upon by the Department of Justice and the ACLU to help with formulation of briefs," Varmus said at the National Cancer Advisory Board meeting Feb. 7.

**BRCA Science and Money Matters**

The BRCA genes were discovered by Myriad, which said it invested more than $500 million into researching the genes and commercializing testing products.

Myriad's sales of BRAC*Analysis*, a product that detects mutations in the BRCA genes to determine increased risks for breast and ovarian cancer, added up

to $405.5 million in 2012.

The test was granted March 6 preventative care designation under the Affordable Care Act, which allows for BRCA testing to be completed at no patient cost for all new health plans (post-March 23, 2010) when an asymptomatic woman has a qualifying family history.

The tests, which cost $4,000 each, made up more than 80 percent of revenue for Myriad last year. However, the value of BRAC*Analysis* is measured not only in sales, but in the databases on BRCA genes and mutations that Myriad's monopoly has enabled the company to collect.

Scientists want access to these data.

A grassroots project called Sharing Clinical Reports is attempting to recreate Myriad's database from the millions of gene test reports that the company sends out. Launched by Robert Nussbaum, chief of the Division of Genomic Medicine at the University of California, San Francisco, the project has only collected about 1.5 percent of Myriad's data, sources said.

"The incentives created by such patents are essential to encourage medical innovation that saves patients' lives," said the Association of American Physicians and Surgeons in a statement, arguing that patents are necessary to encourage private investment in research.

"Valuable cures are being developed based on patents in many medical fields, including adult stem cells—cures that would not be possible without the incentives established by patents."

The justices appeared cognizant of these incentives, discussing at length the importance of industry investments:

"Why would a company incur massive investment if it—if it cannot patent?" asked Justice Antonin Scalia of Christopher Hansen, lawyer for the plaintiff American Civil Liberties Union.

Hansen said that "enormous" public recognition for discoveries is sufficient payback for investors and companies.

"Well, I'm not sure the Court can decide the case on that basis," said Justice Anthony Kennedy. "I'm sure that there are substantial arguments in the amicus brief that this investment is necessary and that makes sense.

"To say, oh, well, the taxpayers will do it, don't worry, is, I think, an insufficient answer."

In a March 31, 2010 report on the impact of gene patents on patient access to genetic tests, the Health and Human Services Secretary's Advisory Committee on Genetics, Health and Society said "patents on genetic discoveries do not appear to be necessary for either basic genetic research or the development of available genetic tests."

The committee found that patents have been "used to narrow or clear the market of existing tests, thereby limiting, rather than promoting availability of testing.

"The substantial number of existing patents on genes and methods of diagnosis also pose a threat to the development of multiplex testing, parallel sequencing, and whole-genome sequencing, the areas of genetic testing with the greatest potential future benefits," the report said.

Other Myriad BRCA patents are in play in this case as well.

The company also owns patents to the other elements that produce the genes, namely, artificial complementary DNA molecules and other isolated DNA molecules that encode the BRCA genes.

Myriad created the cDNAs, which mirror coding sections of the BRCA genes and "primers" used in diagnostics—these synthetic products, some of the justices appear to agree, are patentable.

**cDNAs: Human Manipulation, or Product of Nature?**

The petitioners, attempting to loosen Myriad's hold on cDNAs and the BRCA genes, argued that neither should be patented on grounds that they are products of nature.

"The sequence of the nucleotides is dictated by nature," plaintiffs' attorney Hansen said, addressing the natural properties of cDNAs at the April 15 hearing. "The order that they go in is dictated by nature.

"And the question is whether when the body removes the introns, had the body made something markedly different than what is in nature…"

Justice Kennedy appeared unconvinced, arguing that the functions of cDNAs differ markedly from native, unaltered DNA.

"When I looked at this case, I thought that maybe the cDNA was kind of an economy class gene. It wasn't," Kennedy said. "My understanding is that it may have a functionality that the DNA isolate does not—easier to tag, etc."

Justice Ruth Bader Ginsburg proceeded to question Hansen on the extent of human manipulation to cDNA.

"Everything starts with a natural product, but these others the examples that I gave, you said they involve manipulation," Ginsburg said. "The cDNA can't be characterized as involving manipulation?"

Hansen responded, admitting there is some manipulation, but that nature, not the scientist, is to be credited for the manipulation.

"You've really lost me when you say that it's nature that does the alteration rather than the scientist," Scalia said. "I mean, whenever a scientist does an alteration, he does it, you know, by some force of nature."

The DOJ amicus brief states that artificial DNA molecules, including cDNAs, are human-made interventions eligible for patent protection.

"The resulting cDNA molecule has a different nucleotide sequence than DNA created naturally within the cell, and (because it lacks introns) its 'preferable' to isolated DNA for many laboratory uses," the brief said. "Extending patent protection to cDNAs therefore poses no risk of 'tying up' other uses of the natural raw materials involved in the creation of cDNA."

Myriad's attorney Castanias said that cDNA was created from hundreds of different patient samples to create a consensus sequence.

"Okay," Chief Justice John Roberts said. "You've got the cDNA."

**DOJ: Isolated BRCA Genes are Not Patentable**

According to the Department of Justice's analysis, Myriad's claims to the isolated BRCA genes are invalid, under Section 101 of the Patent Act.

The act provides that an inventor may obtain a patent on "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."

"Isolated DNA is simply naturally occurring DNA that has been extracted from its cellular environment and separated from extraneous material," the department's brief states. "The differences between isolated DNA and native DNA within a cell are merely the inherent and necessary results of removing the DNA from its natural environment.

"Because the removal process is a prerequisite to any exploitation of native DNA, respondents' isolated DNA claims are the practical equivalent of patents on the underlying naturally occurring BRCA genes themselves.

"The fact that isolated DNA has additional applications likewise does not render it markedly different from native DNA.

"The 'additional utility'…is simply the ability of researchers to study and exploit in a laboratory the inherent natural properties that isolated DNA shares with native DNA.

"For two of the composition claims at issue here, the relevant compositions of matter are defined by the natural biological function they perform in the human body: the capacity to express BRCA1 and BRCA2 proteins."

**Snipped Like a Baseball Bat**

Several justices appeared to side with the DOJ on the issue of isolated BRCA genes, using the analogous examples—leaves, plants, and trees—to determine whether the genes should be patentable.

"Suppose there is a substance, a chemical, a molecule in the leaves of a plant that grows in the Amazon, and it's discovered that this has tremendous medicinal purposes," said Justice Samuel Alito to Hansen. "Let's say it treats breast cancer.

"A new discovery, a new way is found, previously unknown, to extract that," Alito said. "You make a drug out of that.

"Your answer is that cannot be patented; it's not eligible for patenting, because the chemical composition of the drug is the same as the chemical that exists in the leaves of the plant."

If picking the leaf off the tree and swallowing it would enable the consumer to reap the benefits, it is not patentable, Hansen argued.

"We agree that you could get a patent on a use of the leaf that is pulled out of the Amazon or a plant that is pulled out of the Amazon," Hansen said. "We don't think you [can] get a patent on the plant itself just because you pulled it out of the ground and took it to the United States."

At this point, Myriad attorney Castanias turned to the time-honored American approach: when the discourse gets complicated, talk baseball.

"I'll use my own simplistic analogy which we offered in our brief and which we offered to the lower court," Castanias said. "A baseball bat doesn't exist until it's isolated from a tree."

"But that's still the product of human intervention to decide where to begin the bat and where to end the bat."

The baseball analogy caught on.

"Here, what's involved is snipping," Justice Roberts said of the isolated BRCA genes. "You've got the thing there and you snip—snip off the top and you snip off the bottom and there you've got it.

"The baseball bat is quite different.

"You don't look at a tree and say, well, I've cut the branch and cut it here and all of a sudden I've got a baseball bat," Roberts said. "You have to invent it, if you will.

"You don't have to invent the particular segment of the strand; you just have to cut it off."

But scientists wouldn't even know where to snip until the Myriad invention, Castanias said.

"Okay, so that's a particular—where you snip,"

Robert said. "We're talking about, though, the patentability of what's left after you've snipped it."

This could be like baking cookies, offered Justice Sotomayor.

"I can bake a chocolate chip cookie using natural ingredients—salt, flour, eggs, butter—and I create my chocolate chip cookie," Sotomayor said. "And if I combust those in some new way, I can get a patent on that.

"But I can't imagine getting a patent simply on the basic items of salt, flour and eggs simply because I've created a new use or a new product from those ingredients."

Justice Elena Kagan chimed in:

"Mr. Castanias, go back to Justice Alito's plant in the Amazon, right, because it takes a lot of ingenuity and a lot of effort to actually find that plant, just as it takes a lot of effort and a lot of ingenuity to figure out where to snip on—on the genetic material.

"But are you saying that you could patent that plant because it takes a lot of effort and a lot of ingenuity to find it?"

Castanias replied: "The plant itself, I think not, Justice Kagan, but I think the question that was posed was whether I could take an extract from that plant."

"Well, but can you patent the thing itself?" asked Kagan.

"The thing itself I would—in that hypothetical, I would say the answer is no," said Castanias.

The justices are expected to rule on the case before the term ends in June.

*Guest Editorial*

## Ruling Likely to Concur with Justice Department Arguments

*By Robert Cook-Deegan*

*The author is the director of the Center for Genome Ethics, Law and Policy at the Duke University Institute for Genome Sciences and Policy. His guest editorial on an earlier appellate court ruling in the case appears in* Aug. 5, 2011 issue *of The Cancer Letter.*

**Q**: What do baseball bats, cancer-fighting tree sap from Amazonian plants, and chocolate chip cookies have in common?

**A**: They were all analogies that Supreme Court justices used to probe the question before them in oral arguments in Association of Molecular Pathology vs. Myriad Genetics (S. Ct. 12-398) on April 15. The oral arguments addressed one deceptively simple question: "are human genes patentable?"

The pantheon of molecular biology was there: Eric Lander, professor of biology at MIT, and DNA co-discoverer James Watson had written two of the 49 amicus curiae briefs.

NIH Director Francis Collins, NCI Director Harold Varmus, and Eric Green, director of the National Human Genome Research Institute, were just a few of the molecular biological luminaries in the audience.

It is always perilous to predict Supreme Court outcomes based on the questions in an hour of seemingly Brownian motion, with questions half-answered before careening off to address a new one.

Every judge except Clarence Thomas asked many questions. All were fully engaged. The attorneys were regularly asked questions that rested on science, and demonstrated the limits of simplifying arcana of molecular genetics to an audience of legal generalists.

Harold Varmus visibly winced, for example, when Greg Castanias, the Jones Day attorney arguing the case for Myriad, declared that scientists had decided where the gene started and ended, and nature had not determined such parameters until the scientists decided the matter. Ouch.

When Justice Kagan drew him out on whether a chromosome, or a liver, or a part of a liver would be patentable if extracted from the body, to his credit Mr. Castanias stuck to his guns and said yes, they would be patent-eligible (but not necessary meet the other patent criteria), but he may have been aiming his guns at the deck of his already fragile life raft.

The general drift of the questions left little doubt that a majority of justices—at least in their questions—wanted to understand why the magical word "isolated" would turn something unpatentable into something patentable, and were not persuaded it made much sense. But they also strongly signaled discomfort with a sweeping decision that might undermine investment incentives in biotechnology.

When Justice Kagan asked Chris Hansen, the ACLU attorney representing the petitioners (those challenging 15 claims in seven of Myriad's patents), why a company would invest in funding such useful R&D without a patent incentive, the body language was clear from one end of the bench to the other: the justices are not going to be satisfied that academic reputation, NIH grants, and Nobel Prizes will supply all the incentives

they want to see in place. They also want the patent incentive to induce private R&D investment in medical products and services.

There was almost no attention to why "human" was in the question, or how decisions in this case might spill over to patents on nucleic acid sequences from other organisms. And nothing at all about who can sue whom in such a patent lawsuit (the question of standing had been removed from questions under consideration, but a justice might nonetheless have asked a question if this were still a lingering concern).

Predictions among those dissecting the proceedings in venues across Washington, D.C., after the event fell into a surprisingly narrow range. The justices seem likely to rule in a way that tracks closely to the arguments of the U.S. government's top lawyer, the solicitor general, who had 10 minutes to make his argument.

The solicitor general's office mediated an often contentious process for deciding that U.S. Patent and Trademark Office practices of granting patents on "isolated" DNA over the past three decades do not comport with the law.

USPTO did not sign onto the solicitor general's brief, but the solicitor general is nonetheless represents the official view of the United States government. The solicitor general's logic appears likely to carry the day: DNA is not patentable subject matter if the only intervention is "isolating" it (whatever that means, and we got no guidance on Monday).

If it is engineered—for example, by removing exons via reverse transcription into cDNA from mRNA, or by tagging it or engineering it, through insertion into a vector, addition of promoters or enhancers, etc.—then it is patent-eligible.

For now, such conclusions are speculative, but the ruling will be apparent soon enough. The case will be decided in the current term, which ends June 30. Since this case was heard in the last two weeks of arguments for the term, the ruling is likewise apt to appear just before the end of the term.

We will have a ruling from the Supreme Court by July.



*The Law*

## Amgen Pays $24.9 Million To Settle Kickback Charges

Amgen Inc. has agreed to pay $24.9 million to settle allegations that it bribed long-term care pharmacy providers to use its Aranesp anemia drug instead of competitor drugs, announced the Department of Justice April 16.

The DOJ charged that the California-based biotechnology company violated the False Claims Act by paying kickbacks to Omnicare Inc., PharMerica Corporation and Kindred Healthcare Inc. in return for implementing "therapeutic interchange" programs that were designed to switch Medicare and Medicaid beneficiaries from a competitor drug to Aranesp.

The government alleged that the kickbacks took the form of performance-based rebates that were tied to market-share or volume thresholds.

As part of the therapeutic interchange program, Amgen distributed materials to consultant pharmacists and nursing home staff encouraging the use of Aranesp for patients who did not have anemia associated with chronic renal failure, according to the allegations.

"We will continue to pursue pharmaceutical companies that pay kickbacks to long-term care pharmacy providers to influence drug prescribing decisions," said Stuart Delery, acting assistant attorney general for the Justice Department's Civil Division. "Patients in skilled nursing facilities deserve care that is free of improper financial influences."

The civil settlement resolves a lawsuit filed under the whistleblower provision of the False Claims Act, which allows private citizens with knowledge of false claims to bring civil actions on behalf of the U.S. and share in any recovery.

The False Claims Act suit, United States ex rel. Kurnik vs. Amgen Inc., et al., was filed in the U.S. District Court for the District of South Carolina.

Delery said that the settlement with Amgen, Inc. was the result of a coordinated effort among the Civil Division, the U.S. Attorney's Office for the District of South Carolina, and the U.S. Department of Health and Human Services, Office of Inspector General.

On the oncology side, last year the company pleaded guilty in federal court in New York for illegally marketing Aranesp as a drug that can be used at off-label doses—a use that the FDA had "specifically considered and rejected," according to a Dec. 19, 2012 DOJ statement.

Amgen paid $762 million, the largest settlement

involving a biotech company in U.S. history, to resolve the criminal liability and False Claims Act allegations.

"Instead of working to extend and enhance human lives, Amgen illegally pursued corporate profits while jeopardizing the safety of vulnerable consumers suffering from disease," Delery said.

"When drug companies improperly misbrand their products, they not only could put individual patients at risk, but they also undermine the federal health care system that protects all of us."

*In Brief*

## Matter wins Szent-Györgyi Prize For Role in Gleevec Development

(Continued from page 1)

Gleevec (imatinib mesylate) contributed to a breakthrough in the treatment of chronic myelogenous leukemia. Gleevec was successfully applied to other malignant cancers by turning off the signal of the protein causing these cancers.

With Gleevec, the outcome of treating CML went from the dismal and often deadly to a nearly 90 percent long-term survival with little or no side-effects.

Matter is the CEO of the Experimental Therapeutics Centre, A*STAR, Singapore, after having spent five and a half years as director of the Novartis Institute for Tropical Diseases.

He was also global head of oncology research and translational research for Novartis Pharmaceuticals, and head of the Novartis Institutes for BioMedical Research. He previously held teaching positions at the University of Basel and the European University Confederation of Rhine.

**TIMOTHY EBERLEIN** was elected president of the **Southern Surgical Association**.

He is chairman of the department of surgery at Washington University School of Medicine in St. Louis. He is the only Southern Surgical Association officer in Missouri.

Eberlein also serves as Bixby Professor and Spencer T. and Ann W. Olin Distinguished Professor, surgeon-in-chief at Barnes-Jewish Hospital and director of the Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine.

---

**Follow us on Twitter: @TheCancerLetter**

---

**AMANDA NICKLES FADER** has joined **Johns Hopkins Medicine** as director of the Kelly Gynecologic Oncology Service and director of the Minimally Invasive Surgery Center in the Department of Gynecology and Obstetrics.

She also holds the appointment of associate professor of gynecologic oncology at the Johns Hopkins University School of Medicine.

Prior to her appointment at Johns Hopkins, she served as an associate director of gynecologic oncology and director of robotic surgery at Greater Baltimore Medical Center.

**GEORGE SALTI** has joined the **Edward Cancer Center** as the co-medical director of the center and medical director of the Edward Hospital Surgical Oncology Program.

Salti was previously an associate professor of surgery at the University of Illinois at Chicago.

He has focused on treating late stage abdominal cancers with hyperthermic intraperitoneal chemotherapy. Only 1,300-1,500 of the procedures are performed annually in the U.S.

**JOHN CONWAY** was promoted to chief business development officer of **Cancer Treatment Centers of America**. He was previously senior vice president of business development and market access.

Conway will be responsible for leading the relationships between CTCA and payors, employers and government organizations, reporting directly to president and CEO Stephen Bonner. Conway has over 25 years of experience in the insurance industry and has been with CTCA for the past five years.

**MASSACHUSETTS GENERAL HOSPITAL** formalized a relationship with **Sovereign Bank**, which committed over $1 million over five years to support cancer research and care at the hospital.

Sovereign will contribute to the MGH Cancer Center through a variety of initiatives, including the MGH Cancer Center Fellowship. This program provides opportunities for fellows to conduct research in laboratories at MGH, Massachusetts Institute of Technology and Harvard University. Sovereign is a division of Santander Holdings USA.

The gift agreement establishes the Sovereign/Santander Hematology/Oncology Fellowship Program Fund for the MGH Cancer Center.

This fund supports the expenses associated with fellows conducting research in the laboratories

at MGH, MIT and Harvard during the research component of their programs.

Sovereign will also support the Friends of the MGH Cancer Center, a volunteer organization that organizes activities, lectures, symposiums for cancer patients and their families—as well as backing a range of other programs and services, including fundraising initiatives and local sports team appearances.

**THE INTERNATIONAL AGENCY FOR RESEARCH ON CANCER** and the **Chulabhorn Research Institute** launched a three-year partnership for collaborative cancer research.

The new agreement was signed today in Lyon, France by IARC Director Christopher Wild and Professor Dr. Her Royal Highness Princess Chulabhorn Mahidol of Thailand. She is the president of the research institute in Bangkok.

Southeast Asia had an an estimated 725,000 new cases and 500,000 cancer-related deaths in 2008. According to IARC, cancer incidence could increase by more than 70 percent over the next 20 years, due to population growth and aging.

**THE NORTH SHORE-LIJ HEALTH SYSTEM** plans to make an initial investment of $175 million to expand its cancer services throughout the New York metropolitan area.

As part of the health system's new initiative, the North Shore-LIJ Cancer Institute now has signed on approximately 150 physician members throughout the New York area in 20 cancer specialties.

A $67 million construction project is already underway at North Shore-LIJ's Center for Advanced Medicine, where 61,150 square feet of interior space is being redeveloped contiguous to the current Monter Cancer Center.

Nearly 40,000 square feet are being added to the current 37,000-square-foot Monter Center, which will now house the system's integrated ambulatory hematology/oncology and chemotherapy treatment services.

In addition, radiation medicine and surgical, gynecologic and neuro-oncology services now delivered at LIJ Medical Center and NSUH will be relocated to the Center for Advanced Medicine, where nearly 50,000 square feet of space has been set aside for three linear accelerators, a gamma knife, stereotactic radiation and brachytherapy services.

**HILARY KOPROWSKI**, a virologist who developed the first successful oral vaccination for polio, died April 11. He was 96.

In 1950, Koprowski was the first to show it was possible to vaccinate against polio.

He self-administered the live-virus oral vaccine he developed before the 1950 clinical trial—about two years before Jonas Salk's injectable version using a dead form of the virus began testing.

Albert Sabin was the first to get the more effective oral version licensed in the U.S.

He was director of The Wistar Institute from 1957 to 1991, and was later a professor in the Department of Cancer Biology at Thomas Jefferson University.