

# Translational tidbits

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### Scripps' Sigma factor

Academic and industry researchers eager to use new tool compounds typically must reproduce synthetic schemes published in academic journals or wait months for reagent makers to list new compounds in their catalogs. To speed up the process, **The Scripps Research Institute** has partnered with **Sigma-Aldrich Corp.** to fast-track access to new research reagents from Scripps chemistry labs.

The deal gives the reagent maker exclusive, early access to tool compounds from six of the institute's chemistry labs. The agreement initially covers IP from labs led by professors Phil Baran, Jin-Quan Yu, Benjamin Cravatt, Carlos Barbas, Philip Dawson and K. Barry Sharpless.

The goal is to have commercial batches of the compounds available from Sigma-Aldrich as soon as a paper describing the compounds is published online.

"Today, when a paper gets published, the reagents aren't necessarily commercially available until 6 to 12 months later," said Amanda Halford, VP of academic research at Sigma-Aldrich. "We want to cut that timeline and make the reagents available exactly at the time of publication."

Scott Forrest, VP of business development at Scripps, said the deal builds on previous collaborations between individual Scripps researchers and Sigma-Aldrich and gives the reagent maker broad and early access to composition of matter IP.

"Traditionally, a tech transfer office signs a series of one-off reagent

**Table 1. Selected public-private partnerships for July 2013.** Europe has had a busy month with public-private partnerships. Significant PPPs announced in July included the U.K.'s SynbiCITE synthetic biology innovation and knowledge center and France's Nano Innovation for Cancer (NICE) consortium to promote the development of nanomedicines. In the U.S., **Sigma-Aldrich Corp.** (NASDAQ:SIAL) announced it will provide undisclosed development funding and exclusively commercialize reagents from six labs at **The Scripps Research Institute**.

Source: Biocentury Archives

Companies	Institutions	Business area	Disclosed value	Purpose
Agilent Technologies Inc. (NYSE:A); GlaxoSmithKline plc (LSE:GSK; NYSE:GSK); Hockley International Ltd.; Lisk and Jones Consultants Ltd.; Microsoft Corp. (NASDAQ:MSFT); New-Food Innovation Ltd.; Oil Plus Ltd.; Oxitec Ltd.; Pulse Medical Technologies Ltd.; Royal Dutch Shell (NYSE:RDS-A); Suterra LLC; Syngenta AG (SIX:SYNN; NYSE:SYT); Visbion Ltd.	Bangor University; Biotechnology and Biological Sciences Research Council (BBSRC); Cardiff University; Engineering and Physical Sciences Research Council (EPSRC); Imperial College London; Newcastle University; Queen's University of Belfast; Royal College of Art; Swansea University; U.K. Technology Strategy Board; University College London; University of Birmingham; University of Bristol; University of Cambridge; University of Edinburgh; University of Glasgow; University of Oxford; University of Sheffield	Other	£5 million (\$7.6 million) received plus £5 million over next two years; another £14 million (\$21.2 million) promised by industry partners	SynbiCITE innovation and knowledge center to translate synthetic biology research into applications
BioAlliance Pharma S.A. (Euronext:BIO); DBI S.A.S.; Nanobiotix S.A. (Euronext:NANO)	Institut Galien Paris-Sud; CEA-Leti	Cancer	€9 million (\$11.7 million)	Nano Innovation for Cancer (NICE) five-member consortium to build a platform to accelerate the development and industrialization of nanomedicine in France
AB Science S.A. (Euronext:AB); Skuldtech	Brain and Spine Institute (ICM); French Alternative Energies and Atomic Energy Commission (CEA); Institut National de la Santé et de la Recherche Médicale (INSERM); Imagine Foundation	Neurology	€8.6 million (\$11.3 million)	Role of Mast Cells in Neurology (ROMANE) consortium to develop AB Science's masitinib (AB1010) to treat Alzheimer's disease (AD)
BioNTech AG; immatics biotechnologies GmbH; BCN Peptides	Association for Cancer Immunotherapy; Beatson West of Scotland Cancer Centre; Eberhard Karls University of Tuebingen; Herlev Hospital; Leiden University Medical Centre; University of Pittsburgh; University Hospital of Geneva; Heidelberg University Hospital; University of Southampton; Technion-Israel Institute of Technology; Vall d'Hebron University Hospital	Cancer	€6 million (\$7.8 million)	Glioma Actively Personalized Vaccine Consortium (GAPVAC) to develop a new class of therapeutic cancer vaccines for brain cancer with grant funding from EU's Seventh Framework Program (FP7)

**Table 1. Selected public-private partnerships for July 2013. (continued)**

Companies	Institutions	Business area	Disclosed value	Purpose
Imaxio S.A.; Preclin Biosystems AG	European Vaccine Initiative; University of Oxford	Infectious	€5.5 million (\$7.2 million)	Bellerophon Project to develop a vaccine against <i>Staphylococcus aureus</i> with grant funding from EU FP7
AstraZeneca plc	Cancer Research UK; University of Cambridge	Cancer	Unavailable	Two-year collaboration comprised of three projects to research tumor mutations and therapies in various cancers
AstraZeneca plc	Tufts University	Neurology	Undisclosed	Collaboration to research discovery-level compounds and validate targets for various brain diseases and disorders, including AD, Parkinson's disease (PD) and autism spectrum disorders
FIT Biotech Oyj Plc	Catholic University of Leuven (KU Leuven)	Cancer; Infectious	Undisclosed	Collaboration to develop immunotherapies based on FIT Biotech's gene transport unit (GTU) technology for transient <i>in vivo</i> expression of mAbs
Ipsen Group (Euronext:IPN; Pink:IPSEY);	Harvard University	Neurology	Undisclosed	Harvard University to discover and develop engineered recombinant botulinum toxins to treat neurological diseases with funding from Ipsen
Kyowa Hakko Kirin Co. Ltd. (Tokyo:4151)	La Jolla Institute for Allergy & Immunology	Autoimmune; inflammation	Undisclosed	Collaboration to research and develop therapies for inflammatory and autoimmune indications
NeoStem Inc. (NYSE-M:NBS)	University of California, San Francisco	Endocrine/metabolic; inflammation; transplantation	Undisclosed	Collaboration to develop human T <sub>reg</sub> cells to treat type 1 diabetes, steroid-resistant asthma and organ-transplant rejection
Pharming Group N.V. (Euronext:PHARM)	China State Institute of Pharmaceutical Industry	Hematology; inflammation	Undisclosed	Collaboration to develop, manufacture and commercialize recombinant human proteins using Pharming's GMP-compliant platform
Sigma-Aldrich Corp.	The Scripps Research Institute	Supply/service	Undisclosed	Sigma-Aldrich to provide development funding and exclusively commercialize reagents from six labs at Scripps
UCB Group (Euronext:UCB)	Lieber Institute for Brain Development	Neurology	Undisclosed	Collaboration to discover compounds to treat cognitive impairment

deals, but this is time and labor intensive," said Forrest. "We were highly interested in finding a reagent partner of choice" to replace the individual deals covering specific reagents.

Under the deal, key compounds in peer-reviewed papers from the six labs will be assigned Sigma-Aldrich catalog numbers at the time of publication. Papers will include hyperlinks to Sigma-Aldrich's ordering website.

It takes up to half a year to scale up and synthesize commercial quantities of most research reagents, but Halford said the deal's early-access terms will give the company sufficient lead time to deliver the compounds by the publication date.

"To scale up the synthesis, we need to work out the process development," said Halford. "The goal is to do this as quickly as possible so there is no delay in the publication."

Financial terms were not disclosed.

The agreement does not give Sigma-Aldrich access to IP for therapeutic candidates and covers only tool compounds and reagent platforms that do not have direct biomedical applications.

"This agreement is focused on reagents that are used in the discovery process," said Halford, adding that the deal has already given the company "a pipeline covering chemical-biology probes and click chemistry from the Sharpless laboratory."

Click chemistry is a modular approach to small molecule design that was originally developed in the early 2000s by Sharpless and other chemists.

Forrest and Halford said the deal was inspired by the success of Sigma-Aldrich's series of zinc-based difluoromethylation compounds from Baran's lab.<sup>1</sup> Those compounds, which came on the market last year, have been widely adopted in medicinal chemistry laboratories in academia and industry as an easy way to fluoridate pharmaceutical leads.

### Diagnosing patent rulings

A common sentiment expressed at last month's [Technology Transfer Summit of North America](#) was that a new patent law and multiple U.S. Supreme Court rulings have collectively altered the way technology transfer organizations (TTOs) approach patenting university inventions. The most profound effects are on diagnostic-based discoveries.

As of mid-March, new patent filings are subject to the Leahy-Smith America Invents Act (AIA), which switches patent priority from 'first to invent' to 'first to file', meaning rights will no longer relate to who made the discovery but to who was the first inventor to file the patent.<sup>2,3</sup>

"First to file rewards people for paperwork, not for early hard work," said a TTO employee who spoke at the meeting under the Summit's [condition of anonymity](#).

She said that because the new law places a premium on filing as soon as possible, TTOs will need to make the financial and manpower commitment to filing patents before researchers may have had the chance to characterize the invention thoroughly. As a result, TTOs may end up spending their already limited resources on preliminary discoveries that later prove to have little value.

However, even under the first-to-invent system, smaller academic institutions, similarly to smaller biotechs, were at a disadvantage because their budgets are more limited than those of large universities and pharmas. Furthermore, many TTOs were already operating under a first-to-file strategy to comply with European patent law.

TTOs are grappling in particular with the patent eligibility of methods claims for molecular diagnostics under Section 101 of the AIA. Much like biotechs in the space, TTOs have been left twisting in the wind by Supreme Court rulings that have essentially punted on the issue of the threshold of patent eligibility under that section.<sup>4-6</sup>

TTO representatives had mixed views on the ramifications of the recent Supreme Court ruling, in *Association for Molecular Pathology v. Myriad Genetics Inc.*, that found isolated DNA sequences were products of nature and could not be patented.

Some TTOs saw *Myriad* as an extra obstacle for diagnostic patents that leaves the picture still murky because the ruling did not settle on a definition of what is a product of nature and what is a true invention.

Others said the ruling provided clarity for the field by providing a line of demarcation between existing genes, which are unpatentable, and artificial constructs of those genes or information about the behavior of a panel of genes, both of which remain patentable.

Although the ruling placed a limit on what could be patented, this clarity helps TTOs advise researchers on whether their genetics-based research is likely to be patentable and have commercial potential.

### PPP roundup

Europe had a busy July with public-private partnerships (*see Table 1, "Selected public-private partnerships for July 2013"*). Significant PPPs announced in July included the U.K.'s SynbiCITE synthetic biology innovation and knowledge center and France's Nano Innovation for Cancer consortium to promote the development of nanomedicines.

The U.K.'s **Engineering and Physical Sciences Research Council**, **Biotechnology and Biological Sciences Research Council** and **Technology Strategy Board** provided £10 million (\$15.2 million) in funding to launch SynbiCITE to translate synthetic biology into application.

The center will receive £5 million (\$7.6 million) in funding over the next two years. It will involve researchers from 17 universities and academic institutions across the U.K., as well as

13 partners from industry.

In France, **BioAlliance Pharma S.A.** is leading the Nano Innovation for Cancer. The five-member consortium received about €9 million (\$11.7 million) in funding through the Strategic Industrial Innovation program of **bpifrance** (formerly OSEO).

The consortium's goal is to build a platform to accelerate the development and commercialization of nanomedicine in France.

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- Usdin, S. *BioCentury* **21**(24), A13–A16; June 17, 2013

### COMPANIES AND INSTITUTIONS MENTIONED

**BioAlliance Pharma S.A.** (Euronext: BIO), Paris, France  
**Biotechnology and Biological Sciences Research Council**, Swindon, U.K.  
**bpifrance**, Maisons-Alfort, France  
**Engineering and Physical Sciences Research Council**, Swindon, U.K.  
**Myriad Genetics Inc.** (NASDAQ: MYGN), Salt Lake City, Utah  
**Prometheus Laboratories Inc.**, San Diego, Calif.  
**The Scripps Research Institute**, La Jolla, Calif.  
**Sigma-Aldrich Corp.** (NASDAQ: SIAL), St. Louis, Mo.  
**Technology Strategy Board**, Swindon, U.K.

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**—Amanda Halford, Sigma-Aldrich Corp.**