Monthly Meeting

2019 Esselen Award to Carolyn R. Bertozzi at Harvard University

2018 Richards Medal Address
By Chad A. Mirkin

How to Allocate Resources to Intellectual Property as a Start-Up
By Katherine Ann Rubino

2019 NESACS Candidates for Election
The field of nanomedicine, broadly defined, uses concepts and tools in nanoscience to develop new ways of tracking and treating disease and making and delivering drugs. In this talk, I focus on one exciting class of nanostructures - spherical nucleic acids, or SNAs - that organize nucleic acids into densely packed and highly oriented three-dimensional forms not seen in nature (Figure 1). SNAs are highly potent gene regulation agents and components of innovative vaccines and cancer immunotherapies.

The reason this field is so important and garners such broad scientific interest is because nanostructures have enabling properties as a result of their size, shape, and composition. In the field of nanotechnology, size is often the focus; but, when compared to the size of small molecules, which have been the primary basis for drugs for decades, nanostructures are actually relatively large. This issue of size is important for two reasons. First, a general tenet of nanotechnology is that when bulk materials are miniaturized to the nanoscale, they take on new properties even if the “large” and “small” materials are compositionally identical. These emergent properties have driven immense technological development, especially in molecular diagnostics, imaging, and cellular studies and assays. They are also beginning to influence the way medicines are developed. Many nanostructures are inherently modular (multi-component) and lend themselves to multifunctionality, something not easily achieved with small molecules. In addition, because they are on the same length scale as many sub-cellular components that are responsible for trafficking medicines, they can easily interface with them.

Nanotechnology is rapidly accelerating the development of nucleic acid therapeutics by enabling key challenges to be overcome that are allowing us to realize the long-standing dream of creating medicines that can target any disease with a known genetic basis. Let us consider conventional nucleic acid medicines. Just 15 years ago, small molecule drugs dominated the top 10 list of the most prescribed drugs. Today, 7 of the top 10 most prescribed drugs are biologics — a remarkable shift in a relatively short period of time. While it is clear that the field of medicine has overwhelmingly transitioned from small molecules to biologics, many people, including myself, believe that the next wave, and perhaps the most promising one, will be the era of nucleic acid medicines. The reasons are straightforward. First, with nucleic acid medicines, disease can be treated at its genetic roots, and we now know many of the genetic origins of disease. Second, once one develops one type of drug, another one can be prepared by simply changing the sequence of the nucleic acid (the identification and synthesis of a whole new molecule is not required). This means that the timeline required for drug development will be significantly shortened, an exciting prospect because much of the cost lies in that process. Another attractive aspect of nucleic acid drugs is that disease can be attacked in many different ways. With gene regulation or knock-down strategies, such as those based on anti-sense and siRNA, one can use nucleic acid medicines to interfere with nucleic acid signatures that produce too much of a particular protein associated with a given disease. By regulating protein expression, a cell can be transformed from a diseased to a healthy one or, in the case of cancer, cause a diseased cell to selectively die or be sensitized towards treatment with chemotherapeutics. However, the opportunities are far greater. Through studies of viral and bacterial disease, we now know specific DNA and RNA signatures that can be utilized to stimulate or suppress the immune system. Therefore, in the lab, we can synthesize DNA or RNA molecules, that if delivered appropriately, can regulate the immune system to treat disease, including many forms of cancer and autoimmune diseases.

With all of these advantages, one might ask why nucleic acid medicines, which have been around for 30 years, are not widely used already. Initially, researchers were extremely excited, but quickly realized that a number of key requirements had to be addressed before such drugs could be successfully implemented. First, there had to be ways to make nucleic acid medicines at a reasonable cost — it turns out that this is no longer a problem, and we can now make large quantities of nucleic acid medicines at pharmaceutical scale. Second, biological pathways through which nucleic acid medicines can function must be thoroughly understood — this, also, is no longer a limiting factor. Through the Human Genome Project and mass sequencing, we now understand and can regulate many of the relevant pathways for a wide variety of disease.

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Fig. 1: Schematic of a SNA with a liposomal core surrounded by a dense shell of highly oriented nucleic acids.
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Cover: 2019 Esselen Award recipient, Professor Carolyn R. Bertozzi, Stanford University (Photo Courtesy of Prof. Bertozzi).

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How to Allocate Resources to Intellectual Property as a Start-Up


When a venture is first getting off the ground, there are a lot of items to be considered. Delegating and protecting resources can be of utmost importance to ensure the future profitability and protection of a start-up. However, knowing when and what resources to delegate money towards, can be an often challenging and thought-provoking conversation. With intellectual property (IP), start-ups need to be aware of potential areas where the fat can be trimmed, as well as areas to tread with caution.

Perhaps, one of the biggest pitfalls start-ups may make is accepting help and input from anybody and anyone willing to offer a hand. When a start-up is first getting off the ground, there are a million different things to check off on a to-do list for the founder. Frequently, less important things get pushed down the to-do list as bigger issues need to be accomplished first, such as making sure payroll will be met each week. In some situations, a problem may arise when a friend, employee, or family member makes a contribution to something that the founder is hoping to protect by a patent a little bit further down the line.

Generally, absent an underlying agreement, patent rights will vest in anybody who contributes towards an invention. The contribution could be tiny, or it could amount to 99% of the invention. The amount of the contribution doesn’t matter, so long as somebody contributed something, they are entitled to patent rights. This can cause problems, because later down the line, a contributor may look for a cut of the pie when the invention is licensed for millions of dollars.

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Tuberculosis (TB) causes more infectious disease-related fatalities than any other human pathogen. Management of TB is a global public health problem that starts with the challenge of accurate diagnosis at the point of care. This presentation will focus on new approaches rooted in chemistry and chemical biology for diagnosis of TB infections in low resource settings. We combine metabolic engineering, smart probe design and microscopic engineering to deliver low cost technologies where they are needed most.

Carolyn Bertozzi is the Anne T. and Robert M. Bass Professor of Chemistry and Professor of Chemical & Systems Biology and Radiology (by courtesy) at Stanford University, and an Investigator of the Howard Hughes Medical Institute. She completed her undergraduate degree in Chemistry from Harvard University in 1988 and her Ph.D. in Chemistry from UC Berkeley in 1993. After completing postdoctoral work at UCSF in the field of cellular immunology, she joined the UC Berkeley faculty in 1996. In June 2015, she joined the faculty at Stanford University coincident with the launch of Stanford’s ChEM-H Institute.

Prof. Bertozzi’s research interests span the disciplines of chemistry and biology with an emphasis on studies of cell surface glycosylation pertinent to disease states. Her lab focuses on profiling changes in cell surface glycosylation associated with cancer, inflammation and bacterial infection, and exploiting this information for development of diagnostic and therapeutic approaches, most recently in the area of immuno-oncology. She has been recognized with many honors and awards for her research accomplishments. She is an elected member of the Institute of Medicine, National Academy of Sciences, and American Academy of Arts and Sciences. She has been awarded the Lemelson-MIT Prize, the Heinrich Wieland Prize, and a MacArthur Foundation Fellowship, among many others.

Major Awards: Fellow of the Royal Society (2018); National Inventor’s Hall of Fame Inductee (2017); American Chemical Society Arthur C. Cope Award (2017); National Academy...
states. Third, the medicines must be able to be delivered to the tissues and cells that matter. A key point I want to make is that having solutions to two of the three of these issues is not good enough. To take advantage of nucleic acid medicines, we need solutions for all three – and that is where nanotechnology and nanomedicine come in.

Despite this progress, the field of nucleic acid medicines is still stymied by the issue of delivery, and the vast majority of nucleic acid drugs that are being developed commercially are for diseases that can be targeted in the liver because, when systemically delivered, the liver is the organ where these medicines naturally accumulate. In my group, we have been asking the questions: what if one could locally deliver nucleic acid medicines directly to diseased tissues? What if one could get them into the eye, the lung, the GI tract, or the skin? There are over 200 dermatological conditions with a known genetic basis, but conventional nucleic acids, linear nucleic acids, will not cross the barriers presented by the skin. Further, what if one could locally stimulate the immune system and train it to fight disease throughout the rest of the body?

About two decades ago, my group discovered a new class of nucleic acids, SNAs, structures made by chemically arranging short snippets of DNA or RNA around a nanoparticle core (Figure 1).1 SNAs have no natural equivalent and, on a sequence for sequence basis, are fundamentally different from their analogous linear structures. SNAs interact with living systems completely differently than linear nucleic acids.8-10 For example, when SNAs are introduced to cells, they are actively and rapidly internalized, despite the fact that linear versions of the same sequence will not enter the same cells (Figure 2).11 SNAs fill the cytoplasm, but they do not enter the nucleus because they are too large. We studied down the origin of this phenomenon and now know that it is a scavenger receptor-mediated process. SNAs enter cells via caveolin-mediated endocytosis, a process that can be tracked by electron microscopy and verified via knock-out cell lines. It turns out most cell lines and tissue types will actively internalize SNAs, creating a tremendous opportunity in drug development.

Thus far, there have been five clinical trials, led by Exicure and Northwestern, focused on evaluating SNA drugs for the treatment of skin diseases like psoriasis and debilitating diseases like Glioblastoma Multiforme (GBM, brain cancer). We are also formulating SNAs as powerful new immunotherapies for different types of cancer. These drugs take advantage of the structure-dependent properties of SNAs that provide them with privileged access to tissues and cells that linear nucleic acids do not enter (unless often-toxic transfection agents are employed). In the case of skin diseases, this is through gels,5,12 in the case of immunotherapies this occurs via a subcutaneous or intratumoral injection,2 and in the case of GBM, through systemic injection.3 Although many of these medicines are potentially field-changing both in terms of how they work and what one can treat, SNAs look particularly promising in the area of vaccinology, where within one structure the key components of a vaccine, adjuvants (immune stimulants) and peptide signatures (for training the immune system to selectively kill diseased cells), can be presented in a structural form that maximizes potency.2, 13-14 This an important point because historically many approaches to vaccine development have focused primarily on toggling the vaccine components as opposed to making structural changes. Through our work, we have systematically shown that structure can make an enormous difference. We studied three classes of SNAs, nearly compositionally identical, but structurally different (Figure 3). The range of responses in over half a dozen animal models of cancer show that among the three structures, the vaccine performance can range from ineffective to curative. The reason for this stark difference may stem from the kinetics of signaling, which is dictated by the chemical structure of the SNA. The adjuvant and peptide signals are in sync in the case of the hybridized structure (which performed the best in all of the models studied), but this is not the case with the other formulations. Taken together, this work shows that chemistry can play an enormous role in nanomedicine development and specifically in vaccine development as 1) structure undoubtedly makes a difference and 2) timing may be everything.
30 years ago and siRNA 20 years ago, much of the research community envisioned that disease as we knew it could be stomped out (“the peak of inflated expectations”). However, critical scientists eventually began to recognize that the implementation of nucleic acid medicines was more difficult than initially thought, and the technology fell into the “trough of disillusionment.” But, if a technology is sound, scientists, who do believe, roll up their sleeves and do the hard work to determine what is really possible. The final product often never reaches the hype of “the peak of inflated expectations,” but significant advances are made, which establish a “plateau of productivity.” In the case of nucleic acid medicines, we are just coming out of the trough and nanomedicines are playing a key role in this process. Companies like Alnylam, Ionis, Excirec, Biogen, and Dicerna have lead compounds deep in the clinic. Some of the first drugs, like Spinnraza and ONPATO-TRO, have been FDA-approved and are used to treat rare diseases like spinal muscular atrophy (or SMA) and polyneuropathy, respectively. SNAs, because they are new therapeutic modalities and delivery systems within one structure, promise to significantly expand this list. We are pressing forward and excited to see what the future holds.

Acknowledgements

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Gustavus John Esselen Award

Prior Recipients of the Gustavus John Esselen Award

1989 - Carl Djerassi, Stanford University. Synthesis and Promotion of the First and Most Common Birth Control Hormone.
1981 - Kary B. Mullis. The Discovery of Polymerase Chain Reaction (PCR) for the Replication of DNA Molecules.
1972 - Bruce D. Roth, Pfizer Global Research & Development. The Discovery and Development of Liptor® (Atorvastatin Calcium).
1969 - Richard D. DiMarchi, University of Indiana, Chemical Biotechnology as a Means to Optimal Protein Therapeutics.
1968 - Michael A. Marletta, University of California at Berkeley, Nitric Oxide in Biology: From Discovery to Therapeutics.
1967 - John A. Katzenellenbogen, Swanlund Professor of Chemistry, University of Illinois at Champaign-Urbana, Estrogens and Estrogen receptors as a Nexus of Chemistry and Biology in Health and Disease.
1966 - Chad A. Mirkin, Director of the International Institute for Nanotechnology, George B. Rathmann Professor of Chemistry, Professor of Biomedical Engineering, Professor of Biological and Chemical Engineering, Professor of Medicine and Professor of Materials Science and Engineering, Northwestern University. Nanostructures in Chemistry, Biology, and Medicine.

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Intellectual Property

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each year. A way this can be avoided is to have clear cut employment agreements in place that specify assignment agreements for inventions or contributions made by employees. Assignment agreements are a typical practice, that can vest all rights in invention made by an employee back to the employer. These agreements can save time and money and prevent future awkward conversations. Furthermore, these arrangements are commonplace in the workplace, and help define the expectation for the employee.

Another area where start-ups may try and cut costs is by failing to formulate an IP strategy. Again, as a start-up first starts out, a million decisions have to be made. Frequently, a founder may put off consulting with an IP attorney until later, at a more convenient time. However, as the company grows and develops, and more employees are added, the number of people knowing about the IP grows, as does the chance for a potential disclosure.

Working for a start-up can be an exciting venture with lots to develop and innovate. Frequently an employee may excitedly tell a friend or family member about the cool things they did at work today, or even worse may disclose something not yet protected by a patent at a seminar or trade show. These types of disclosures may be devastating because they can increase the difficulty in later obtaining a patent or disclose costly trade secrets. In the U.S. disclosing your idea such as offering products for sale, publishing an article pertaining to your invention, or disclosing your product at a trade show may trigger a one-year clock to file a patent application. Recently, the Supreme Court even ruled that secret sales count as prior art and trigger the one-year clock to file a patent. Having a clear IP strategy in place can help put mechanisms and channels in place to protect innovations and ensure there is a plan for filing patents. This problem can also be mitigated by filing a provisional patent application on an invention, which holds the place for a non-provisional patent application to be filed within one year, while the invention is refined. Often times, provisional applications can be a great starting place for start-ups as they cost less money to file than non-provisional applications and allow the invention to be enhanced and updated, as for example, engineering bugs are worked out. Filing provisional applications can be part of an IP strategy that allows for a start-up to then pursue non-provisional applications that show great success and promise.

And to mirror the last pitfall, another problem a start-up may face once they do file provisional applications, is to fail to pursue non-provisional applications within one year. Provisional applications are placeholders, preserving an early priority date, that require a non-provisional application to be filed within one year. Failure to file a non-provisional application can result in abandonment of the application and loss of that original priority day. Often times, this would mean the need to file a new application and receive a new priority date. By now it may be more than one year

Esselen Award

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Biology, University of California, Berkeley. Re-writing the Code of Life: The Impacts and Ethics of Genome Editing

2019 – Carolyn A. Bertozzi, Howard Hughes Investigator, Anne T. and Robert M. Bass Professor of Chemistry and Chemical and Systems Biology (by courtesy), Stanford University. Chemical Approaches to Problems in Global Health

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Karen Allen
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Petition Candidates: “Any group comprising two per cent or more of the Northeastern Section may nominate candidates....” See NESACS website for details. ◇
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of Sciences Award in the Chemical Sciences (2016); Ernest Orlando Lawrence Award of the U.S. Department of Energy (2015); UCSF 150th Anniversary Alumni Excellence Award (2015); Hans Bloemendal Award (Radboud Univ. Nijmegen) (2013); Heinrich Wieland Award (2012); Tetrahedron Young Investigator Award (2011); Lemelson-MIT Prize (2010); Albert Hofmann Medal (Univ. Zurich) (2009); Harrison Howe Award (2009); W. H. Nichols Award (2009); Willard Gibbs Medal (2008); Roy L. Whistler International Award in Carbohydrate Chemistry (2008); Li Ka Shing Women in Science Award (2008); Ernst Schering Prize (2007); T.Z. and Irmgard Chu Distinguished Professorship in Chemistry (2005); Havinga Medal, Univ. Leiden (2005); Iota Sigma Pi Agnes Fay Morgan Research Award (2004); Irving Sigal Young Investigator Award of the Protein Society (2002); Fellow of the American Association for the Advancement of Science (2002); Donald Sterling Noyce Prize for Excellence in Undergraduate Teaching (2001); UC Berkeley Distinguished Teaching Award (2001); ACS Award in Pure Chemistry (2001); Merck Academic Development Program Award (2000); UC Berkeley Department of Chemistry Teaching Award (2000); Presidential Early Career Award in Science and Engineering (PECASE) (2000); MacArthur Foundation “Genius” Award (1999); Camille and Henry Dreyfus Teacher-Scholar Award (1999); Arthur C. Cope Scholar Award (ACS) (1999); Beckman Young Investigator Award (1998); Prytanean Faculty Award (1998); Glaxo Wellcome Scholar (1998); Research Corporation Research Innovation Award (1998); Office of Naval Research Young Investigator Award (1998); Horace S. Isbell Award in Carbohydrate Chemistry (ACS) (1997); Alfred P. Sloan Research Fellow (1997); Burroughs Wellcome New Investigator Award in Pharmacology (1997); Pew Scholars Award in the Biomedical Sciences (1996); Exxon Education Fund Young Investigator Award (1996); Camille and Henry Dreyfus New Faculty Award (1995)

Intellectual Property
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don down the line and someone else may have already invented your invention.

As of 2013, with the passage of the America Invents Act (AIA), the U.S. now operates on a first to file system, whereby the first inventor to file a patent application obtains the rights to that invention. Abandonment of an application may not mean abandonment of the invention, but may mean abandonment of an earlier priority date and thus someone else in the interim may file an application. Ultimately, this may result in an inability to obtain a patent. Ensuring that deadlines are met and that non-provisional applications are timely filed is essential for any start-up.

Finally, another potential problem for start-ups can include “relying” on trade secret protection in lieu of filing a patent. While innovations that are patented can be protected instead under trade secret law, having strict measures in place to ensure adequate protection is paramount. Often, trade secret law is complex and requires pure confidentiality. In addition, trade secrets require additional steps such as educating staff about trade secret protections, as well as ensuring staff compliance with non-disclosure agreements. Employees who break confidentiality often have to be let go and can sometimes cause logistical nightmares. Furthermore, with passage of the Defend Trade Secrets Act (DTSA) in 2016, an owner of a trade secret has the right to sue in federal court for trade secret misappropriation. However, in order to be able to sue under DTSA you must show you had a trade secret to even begin with. Failing to provide adequate documentation or proof that a trade secret even exists can be devastating and ultimately result in the loss of the ability to bring suit against a potential leaker. Having a clear IP strategy that outlines which inventions will be protected by trade secrets, and which inventions will be protected by patents can be paramount in ensuring the future vitality of a start-up.

To summarize, there are many different pitfalls that can create problems for start-ups as they are first getting off the ground. Many of these potential problems can be greatly minimized by formulating a strategic plan to create an IP strategy that will provide the most benefit for the start-up, and ensure future success for many years to come.

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Calendar

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http://www.NESACS.org

Note also the Chemistry Department web pages for travel directions and updates. These include:
http://www.bc.edu/schools/cas/chemistry/seminars.html
http://www.bu.edu/chemistry/seminars/
http://www.brandeis.edu/departments/chemistry/events/index.html
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April 1
Prof. Alice Ting (Stanford)
Harvard, Pfizer Lecture Hall, 4:15 pm

April 2
Prof. David Sarlah (U. Illinois-Urbana-
Champaign)
Boston College, Merkert 130, 4:00 pm

April 3
Prof. Andrew Ellington (Univ. Texas-Austin)
Boston College, Merkert 130, 4:00 pm

April 4
Prof. Jennifer Doudna (UC-Berkeley)
Boston University, Metcalf 113, 4:00 pm

April 8
Prof. Tsehiek Yoon (UW-Madison)
BU, Metcalf 113, 4:00 pm
Prof. Adam Willard (MIT)
Brandeis, Gerstenzang 124, 3:40 pm
Prof. Ben Cravatt (Scripps Research Institute)
Harvard, Pfizer Lecture Hall, 4:15 pm

April 9
Prof. Jerome Robinson (Brown)
U. New Hampshire, Parsons N104, 11:10 am

April 10
Prof. Shana Kelley (Univ. Toronto)
Boston College, Merkert 130, 4:00 pm
Prof. Paul Chirik (Princeton)
MIT, 4-370, 4:15 pm

April 11
Organic Synthesis Symposium
MIT, 6-120, 4:00 pm

April 12
Prof. John Tsavalas (U. New Hampshire)
UMass-Lowell, Olney 316, 3:30 pm

April 16
Prof. Steven Townsend (Vanderbilt)
Tufts, Pearson P-106, 4:30 pm
Prof. Fang Liu (Columbia)
U. New Hampshire, Parsons N104, 11:10 am

April 17
Prof. David Baker (Univ. Washington)
Harvard, Pfizer Lecture Hall, 12:55 pm
Prof. Christopher C. Cummins (MIT)
MIT, 4-370, 4:15 pm

April 18
Prof. Maciej Walczak, (Univ. Colorado)
MIT, 6-120, 4:00 pm

April 22
Prof. Ksenia Bravana (Boston Univ.)
Boston University, Metcalf 113, 4:00 pm
Prof. David Reichman (Columbia)
Harvard, Pfizer Lecture Hall, 4:15 pm
Prof. Aviv Regev (Broad Institute)
MIT, 4-270, 4:00 pm

April 23
Prof. Amanda Hargrove (Duke)
Boston College, Merkert 130, 4:00 pm
Dr. Sunney Xie (Harvard)
Single cell genomics: when stochasticity meets precision
MIT, 6-120, 4:00 pm
Prof. Justin Kennemur (Florida State)
U. New Hampshire, Parsons N104, 11:10 am

April 24
Prof. Kyoko Nazaki (Univ. Tokyo)
Homogeneous catalysis for organic polymer synthesis
Boston College, Merkert 127, 4:00 pm
Prof. Melanie Sanford (Univ. Michigan)
MIT, 4-370, 4:15 pm

April 25
Prof. Kyoko Nazaki (Univ. Tokyo)
Coordination copolymerization of olefins with polar monomers
Boston College, Merkert 127, 4:00 pm
Prof. Dale L. Boger (Scripps Research Institute)
MIT, 6-120, 4:00 pm

April 26
Prof. Kyoko Nazaki (Univ. Tokyo)
One-step formation of multiple bonds for the synthesis of novel pi-conjugated molecules
Boston College, Merkert 127, 4:00 pm
Prof. Kimberly Hamad-Schifferli (UMass-Boston)
Engineering the nano-bio interface for applications in infectious disease
UMass-Lowell, Olney 316, 3:30 pm

April 29
Prof. Elon A. Ison (North Carolina State)
Boston University, Metcalf 113, 4:00 pm
Prof. Ryan Hili (York University)
Brandeis, Gerstenzang 124, 3:40 pm
Prof. Jonathan Owen (Columbia)
Harvard, Pfizer Lecture Hall, 4:15 pm
Prof. Dennis A. Dougherty (Caltech)
MIT, 4-270, 4:00 pm

April 30
Dr. Juan DePablo (Univ. Chicago)
MIT, 6-120, 4:00 pm

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