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The Foundry Model is Coming to Molecular Diagnostics, Courtesy of the Semiconductor Industry.

By Wayne Woodard

OVERVIEW

In 1981, in a lab on the campus of the University of Southern California, researcher Danny Cohen likely had no idea that the formation of his group called MOSIS (Metal Oxide Semiconductor Services) would launch a service that would revolutionize the semi-conductor industry. Indeed, that same idea is now poised to fundamentally transform the biotechnology sector.

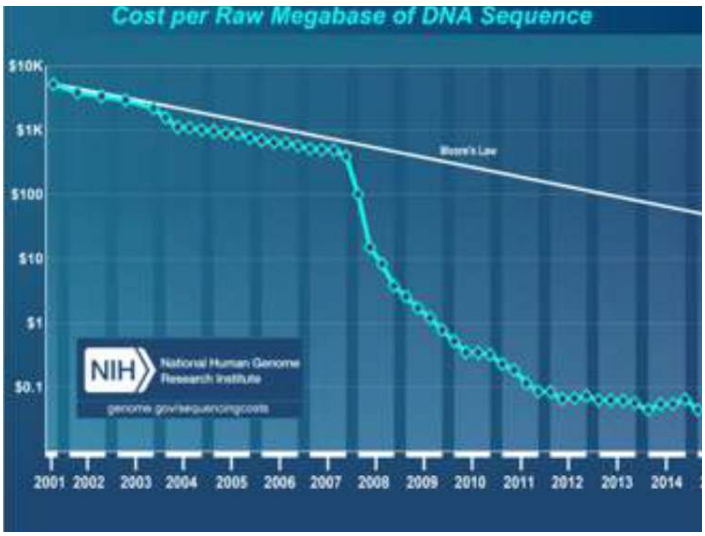
By the mid 1980's, MOSIS had evolved into what is today considered the semiconductor "foundry model." The foundry model leverages the commonality of manufacturing techniques in a process-oriented industry across several clients' innovations to produce incredible technology as a variable cost versus a fixed cost on each company independently. By consolidating multiple customer projects onto shared wafers, chip production costs were slashed.[1] In 1987 Taiwan Semiconductor Manufacturing Corporation (TSMC) was formed. A MOSIS competitor, TSMC is dedicated to assisting the world's innovators with excellent client services, incredible quality, and access to the state of the art in semi-conductor manufacturing technology and capabilities. Today, TSMC along with 4 of their closest rivals represent over $43 billion in annual revenues by assisting all types of innovators from the largest fabless semiconductor companies to the best and brightest 10-person Silicon Valley start-ups.

Fast-forwarding to today, in my opinion, the underlying industry conditions that spawned MOSIS and TSMC to drive the foundry model are arguably the same as those facing molecular diagnostics today: PACE, LEVERAGE and COST.

THE 3 DRIVERS THAT SPAWNED GROWTH OF THE FOUNDRY MODEL

Pace of Innovation

The first driver is the pace of innovation (in semiconductor terms, this is the often referred to Moore's law). Even by the mid 1980's there was a seemingly impossible pace of change and innovation in the semiconductor industry and Moore's Law was used to describe a doubling every two years in the number of components per integrated circuit. Fundamentally, this was translated into greater complexity and opportunity with each new chip. Now this is being replicated in Molecular Diagnostics as the advent of NextGen Sequencing plummets sequencing costs and gives rise to an enormous amount of data, and vast opportunities to better understand and control disease. Indeed, the reductions in sequencing costs (per mega-base) are outpacing Moore's law (see graph below).



source: genome.gov/sequencingcosts

[1] https//www.isi.edu/about/history/timeline/

Leverage of Commonality

The second driver is the similarity in leverage available from common, non-competitive, manufacturing techniques.

By the mid 1980's the techniques used to manufacture a wafer and eventually a semiconductor chip were largely consistent. There are always technique variations and recipes that remain trade secrets to the clients. However, in general the basic process is consistent (Bare wafer, pattern formation, isolation, gate formation, contact formations and interconnect). The powerful intellectual property comes from the creativity of the innovators' novel designs as it relates to its intended use.

In the world of Molecular Diagnostics the situation is largely the same, in that noncompetitive techniques for manufacturing are typically very similar. Formulating, filling and finishing of reagents and consumables follows commonly accepted biology lab/manufacturing norms while accounting for scale and variations in recipe, concentration values and application. In this case, the incredibly innovative intellectual property is once again derived from the application of these various techniques and materials in novel ways.

Increasing Cost of Innovation

Finally, the third similarity between current molecular diagnostics and 1980's chip fabrication is the cost of constructing the capability to support the innovators from pilot lots through full-scale volume manufacturing and supply chain support. Rock's Law[2] (also known as Moore's second law) is that chip R&D, manufacturing, and test costs expand exponentially over time, even as the cost to the consumer falls. By this law, the cost of a new semi-conductor chip manufacturing plant doubles every four years.

In today's environment, the cost to construct and support a competitive, state of the art semiconductor facility exceeds $14 billion dollars.[3] This poses a significant financial challenge and limits the number of companies who can justify this investment to just a handful, most of which are foundries and not product companies.

On the surface, comparing the disparate entry costs of facilities between Molecular Diagnostics and semiconductor fabrication are not fair. On a relative impact basis however, the cost of compliance and skyrocketing cost of research and development is absolutely a reason for concern. These realities are leaving CEO's and COO's with empty budgets for clean room manufacturing facilities equipped with state of the art equipment, all managed under the control of a world-class quality system in a complex and changing regulatory environment. The costs to participate in these markets at economies of scale are rising rapidly.

LIFE SCIENCE OUTLOOK – THE NEED FOR A FOUNDRY MODEL

According to Deloitte's 2017 Life Science outlook the fastest growing sectors for growth through 2020 is the in-vitro diagnostics market. With a 5.1% CAGR this market will be more than $67 billion in 2020. In the same report, Deloitte also points out that R&D spending in that sector in 2015 grew a whopping 38% YoY and has a CAGR of 4.3% through 2020. Development costs in 2012 ranged from as little as $0.5M with one-year development time for a simple test, to $2.5M and two and a half years of development for multi-markers.[4] However, the total development costs over five years were estimated at $4.6M per test and this does not include use studies or marketing and sales costs. While it is unclear at this time whether manufacturing and test costs are approaching Rock's Law, current R&D spend for in-vitro diagnostics is exceeding it.

What is clear is the decision to develop a single assay can be a matter of survival for a small start-up, while better-funded organizations developing multiple assays will be subject to significant expenses.

When the semiconductor industry was faced with nearly identical problems in the mid- 1980's, they turned to the foundry model. Not only did this model answer the challenges of pace, leverage and cost, it accelerated the innovation cycles faster than anyone ever imagined. As a case in point, consider the cell phone. The pace of innovation and technology in phones was fueled by the incredible flexibility and leverage that the foundry model afforded. Consumers began upgrading to new phones every 18 months to take advantage of new technologies and applications.[5] Companies around the world suddenly could create a new chip, have it manufactured and tested in a foundry, and then sold to the largest players in the industry like Apple and Samsung without ever developing a manufacturing process themselves to deliver it! In fact, according to a McKenzie study and data from iSupply the wireless market will account for over 32% of Semiconductor capacity in 2017. Approximately 62% of this market is produced in semiconductor foundries around the world.[6]

WHAT WE HAVE LEARNED

To bring this full circle and back to the Molecular Diagnostic market, what have we learned?

- New in-vitro assays are being driven by rapid innovations empowered by the slashing costs of NextGen sequencing and democratization of sequencing date (Moore's law). The research cost to develop assays is rapidly increasing (Rock's Law).

[2] The New Quantum Universe, 2nd Edition 1987. Tony Hey and Patrick Walters. Cambridge University Press (ISBN-13:9780521564571 / ISBN-10:0521564573

[3] http://www.tomshardware.com/news/samsun-14-billion-chip-plant,29058.html

[4] Source: Diaceutics Research, "The Public Side of Diagnostics: Major Names and Emerging Markets" 2012.

[5] https://www.gsma.com/publicpolicy/wp-content/uploads/2012/03/ environmobilelifecycles.pdf

[6] McKinsey&Company 2013. McK on Demiconductors_Issue 3_2013.pdf

- The semiconductor industry in the mid-1980's faced similar challenges in pace, leverage and costs. The foundry model relieved these challenges but the process also unleashed even faster innovation.
- Unlike semiconductors, highly regulated governmental quality processes additionally challenge the in-vitro assay market. These are further exacerbated by the ongoing changes in the macro-healthcare environment.
- The overall cost to develop the operational excellence, facilities, and regulated quality systems needed to bring in-vitro applications to the market are high.
- Without a solution in the Molecular Diagnostic market, the pace of innovation will likely be slowed as access to capital resources is constrained by the increasing need for R&D investment to compete in the markets.
- A foundry model for the in-vitro diagnostics market that distributes costs across the players may alleviate risk. However, if it follows the semi-conductor model it may also unleash faster innovation.

SUMMARY

Some may consider the leap from the foundry model of the semiconductor industry to the molecular diagnostics industry a stretch. However, after 30 years of focusing on the complexities of various supply chains in three different high technology industries including biotech, to me the homologies are unsettling. The pace of innovation, the leverage of commonality and the pressures of increase costs of innovation are the drivers of the molecular diagnostics industry. These indicators provide an amazingly consistent correlation to the pattern of semiconductor fabrication in the 1980's. To quote Mark Twain, "History doesn't repeat itself, but it does rhyme…."

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