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Transparency: The ultimate validation of antibody

- Understanding how the market forces created antibody chaos

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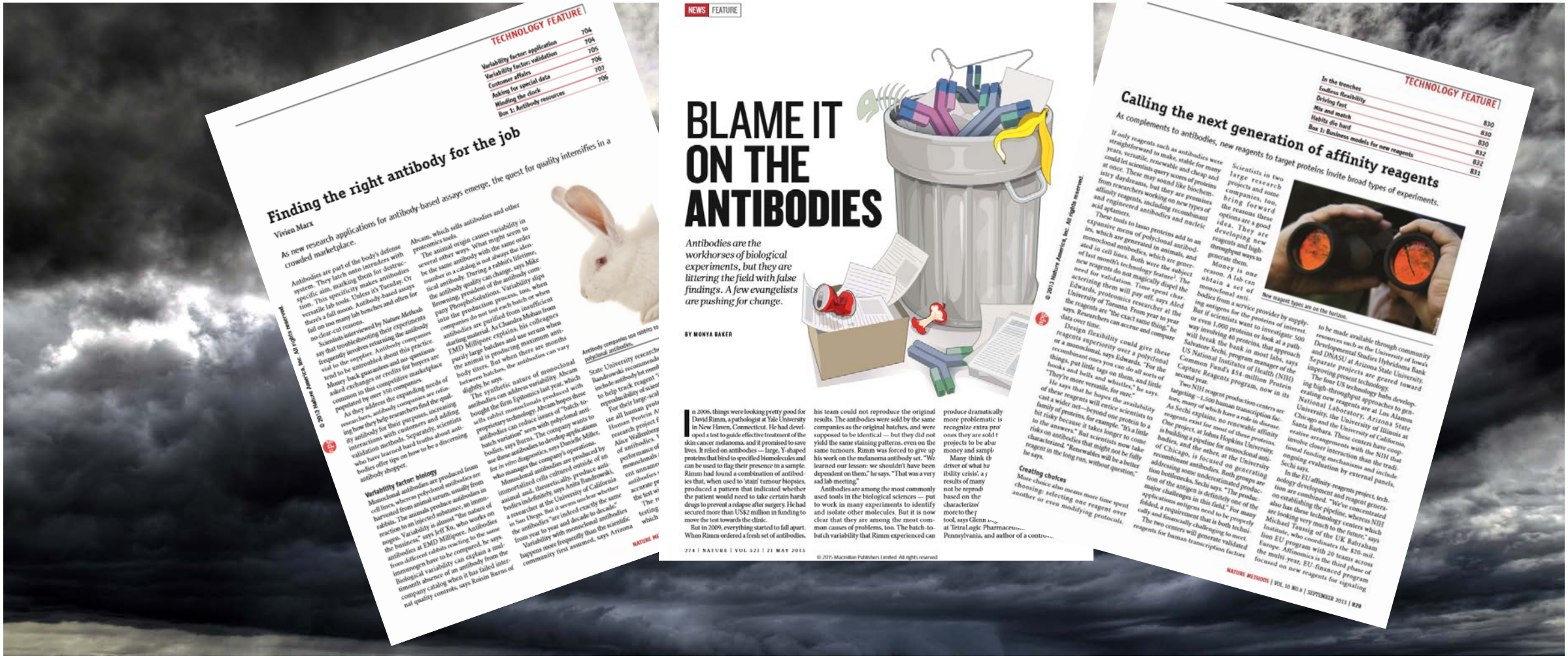
2015 is a stormy year in Antibody world



TECHNOLOGY FEATURE

Finding the right antibody for the job

Vivien Marx

As new research applications for antibody-based assays emerge, the quest for quality intensifies in a crowded marketplace.

NEWS FEATURE

BLAME IT ON THE ANTIBODIES

Antibodies are the workhorses of biological experiments, but they are littering the field with false findings. A few evangelists are pushing for change.

BY MONYA BAKER

TECHNOLOGY FEATURE

Calling the next generation of affinity reagents

As complements to antibodies, new reagents to target proteins invite broad types of experiments.

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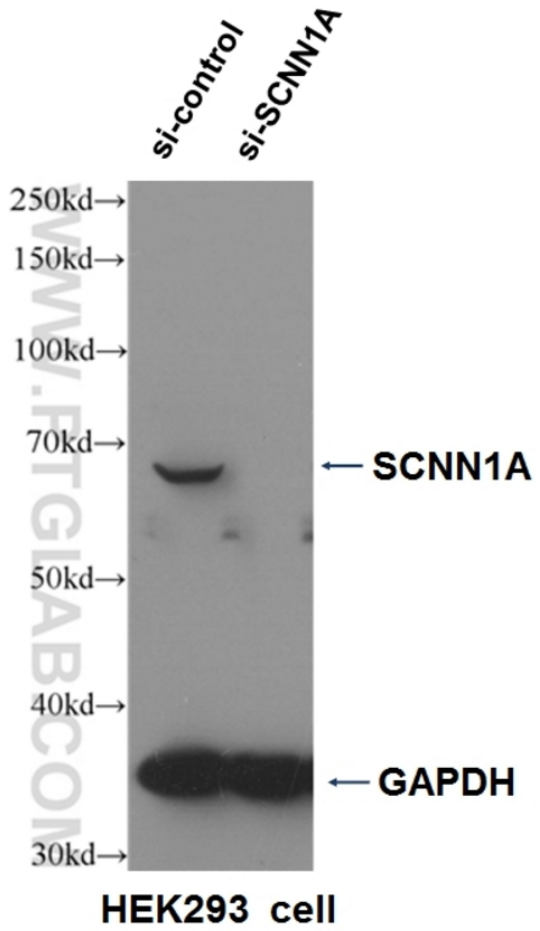
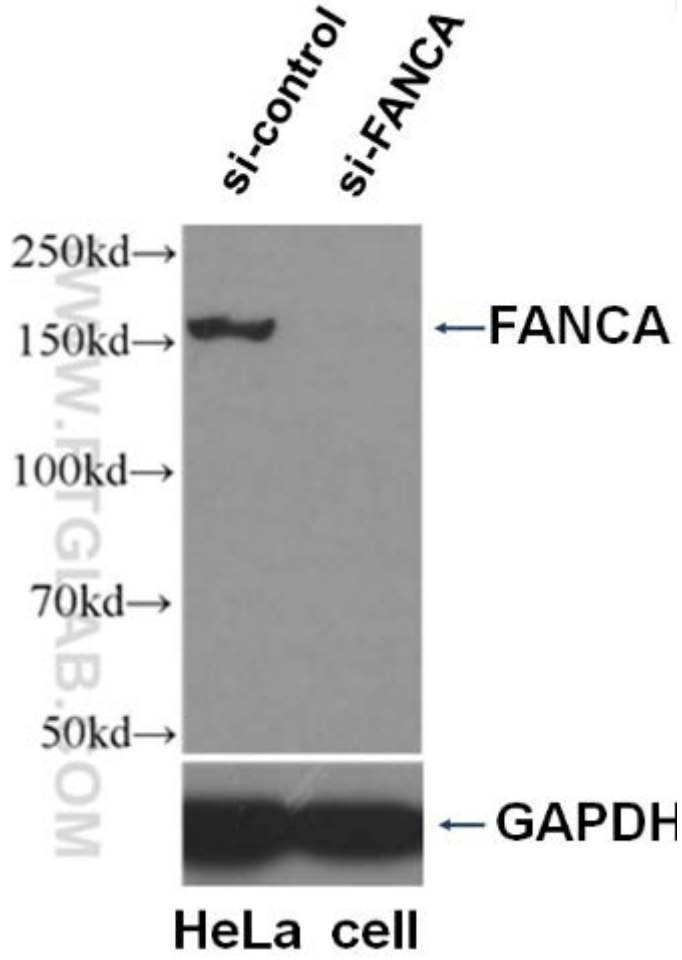
Key question: does this antibody really bind what it supposed to?





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Responses from Scientific Community

1. Calling for a national registry of antibodies
2. Calling for "golden standards" such as knock-down (siRNA), knockout (traditional or current Cas9-CRISP) or direct identification of antibody-bound antigen by Mass Spectrum.
3. Calling for users be aware.

These are all necessary and essential corrections. However, none of these are new technologies. They've existed for some time now, and been proposed over and over, so we must ask ourselves: *why aren't they already in place?*

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The good old days, or not?

Stage 1: The market emerges

In the pre-genomic era, scientists made their own antibodies. Colleagues in the same field often shared antibodies, but slow and labor-intensive.

Stage 2: Specialty manufacturers enter

Facing the widespread need to study novel proteins revealed by Human Genome Project, companies began to create antibodies in anticipation of future market demand. However, antibody usage is specialized and demand varies. As such, manufacturers produced a wide range of antibodies, relying on the success of one or two products to fund continuing R&D.

Stage 3: Super IT Distributors enter

By offering antibodies from a variety of manufacturers, distributors provided scientists with a single hub that met their antibody needs. At the same time, manufacturers were free to devote more resources to production, rather than marketing. In an ideal scenario, these partnerships would benefit all three parties.

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The 4 forces working in the antibody market

1. The Scientists (consumers who uses antibodies)
2. Manufacturers (the people who makes antibodies)
3. The distributors (re-branders)
4. The capital investments (the people who……)

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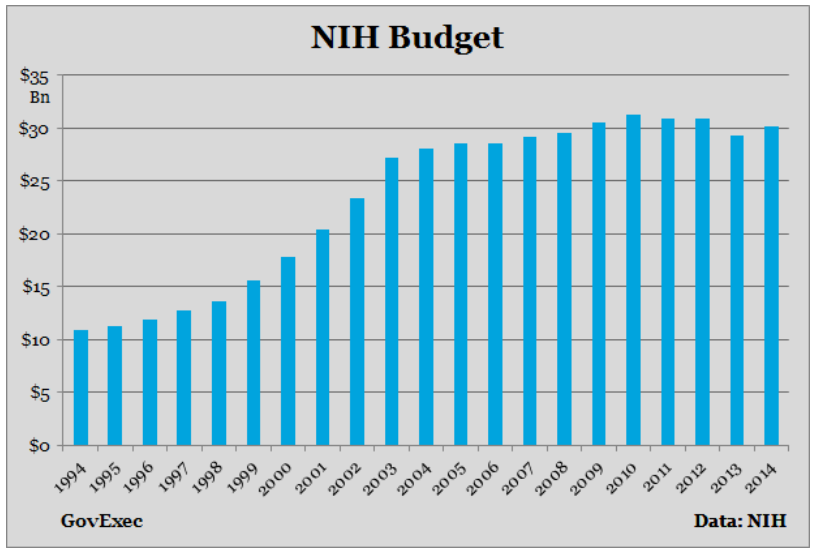
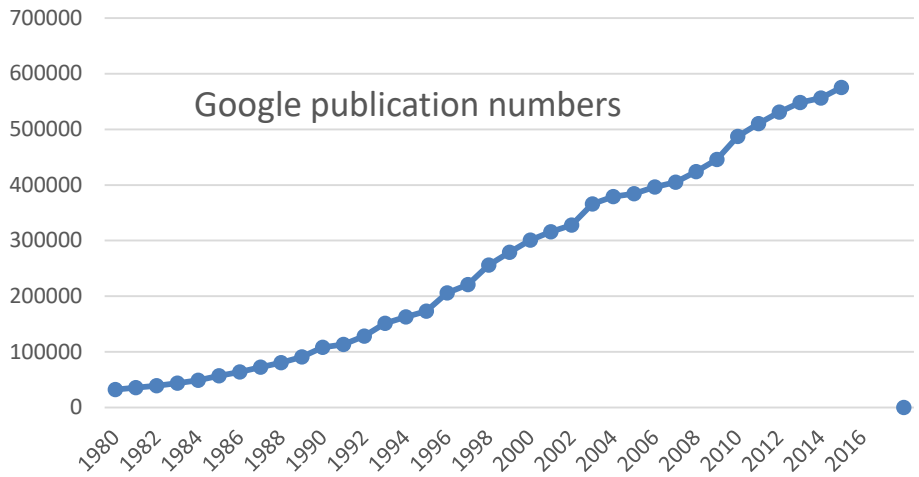
Force #1, The Consumer

A quote from Nature Editorial:

Next milestone of human genomics is to decode the structure and function of proteins, the end product of the genome, i.e. the human proteomics.

With the start of Proteomic projects, antibody demand went up dramatically, yet, the funding did not.





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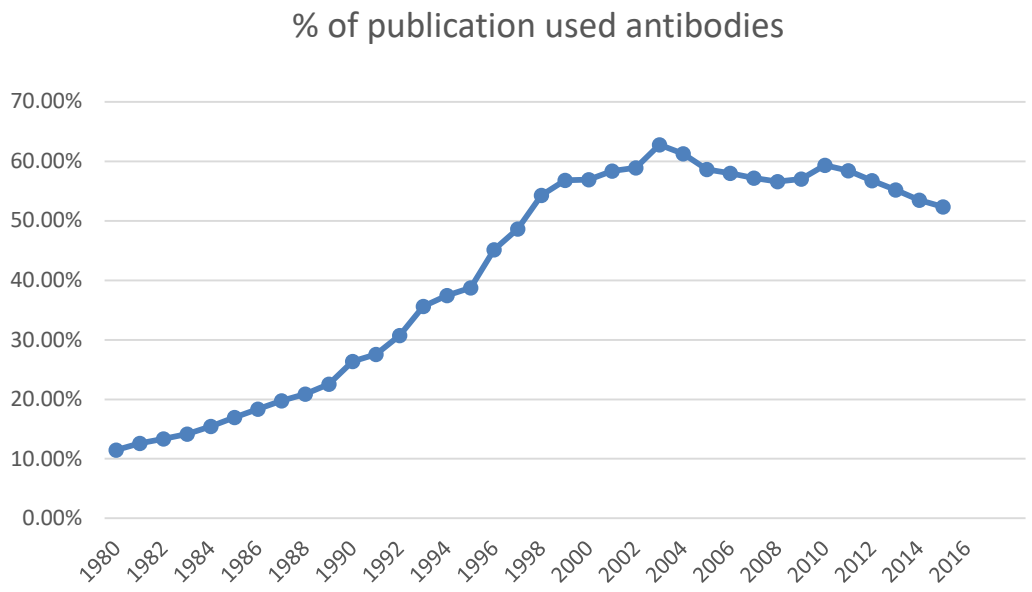
The force #2 Commercial antibody Manufacturers



Is commercial antibody necessary? The answer is yes.

1. Antibodies become immediately available, saves time
2. Antibodies evenly distributed to scientific communities no monopoly
3. Cost dramatically down so scientists can do more with the grant.

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Force #3, The super IT global distributors (Re-brander)

Benefit:

1. find those hard to find antibody
2. Cross custom barrier between countries.
3. Supposedly to decrease marketing and distribution cost

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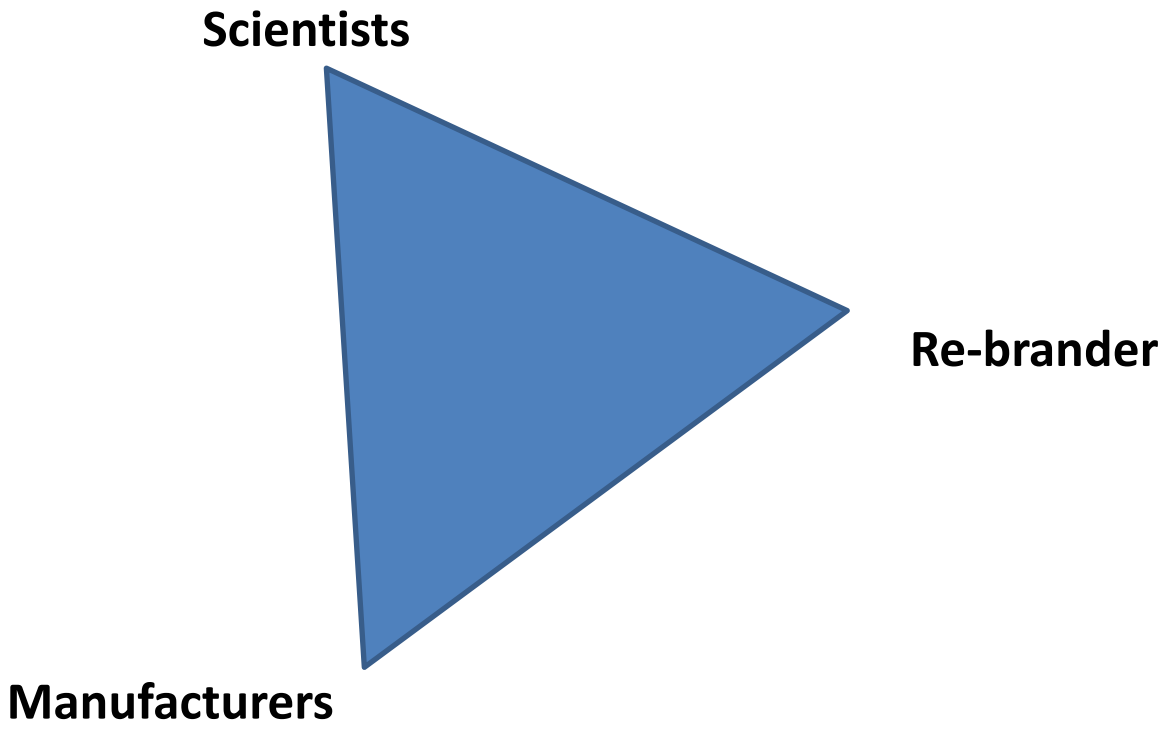

This fundamentally untenable business situation has been masked by a flood of entry of small antibody producers relying on capitals from investors, but the core issue remains: revenues have not risen, costs have not fallen, but the market has a new middleman taking a cut.

Something has to give, unfortunately it is the Quality

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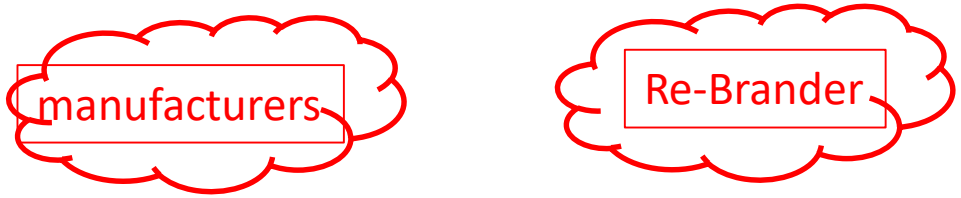
When in doubt, ask Carl Marx

The conflicts between of the productivity and relations of production



Carl Marx, Preface to the Critique of Political Economy (1859)

At a certain stage of development, the material productive forces of society come into conflict with the existing relations of production or – this merely expresses the same thing in legal terms – with the property relations within the framework of which they have operated hitherto. From forms of development of the productive forces these relations turn into their fetters. Then begins an era of social **revolution**.

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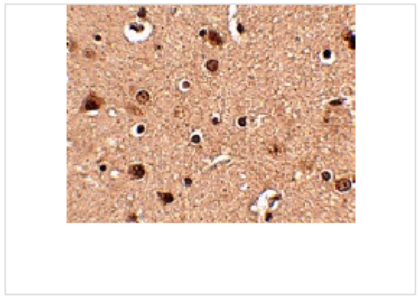
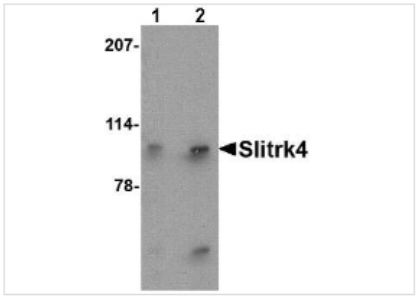
Distributors (Re-brander)'s Headache

Re-Branding created a chaos in antibody identity, effectively stripe any manufacturers responsibility. Not only the same antibody are sold by multiple companies without telling customers, some companies even are selling the same antibody under multiple catalog number not realizing they are the same.

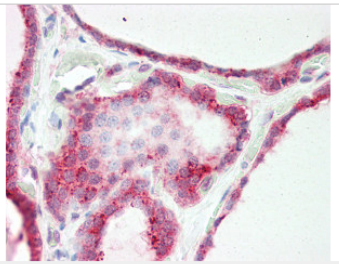




Datasheet | Specific References | Protocols

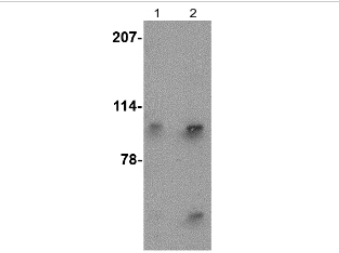
Overview — Visit the Product Wall for Abreviews and Q&A

Product name	Anti-SLITRK4 antibody See all SLITRK4 primary antibodies ...
Description	Rabbit polyclonal to SLITRK4
Specificity	ab67308 is predicted to have no cross-reactivity to other SLITRK proteins.
Tested applications	ICC/IF, WB, IHC-P ▸ more details
Species reactivity	**Reacts with:** Mouse, Rat, Human
Immunogen	A 14 amino acid synthetic peptide from near the amino terminus of human SLITRK4.



Immunohistochemistry (Formalin/PFA-fixed paraffin-embedded sections) - Anti-SLITRK4 antibody (ab115690)

ab115690 at 5ug/ml staining SLITRK4 in Human thyroid tissue by immunohistochemistry (FFPE). Following primary incubation slides were incubated with biotinylated goat anti-rabbit IgG secondary antibody, alkaline phosphatase-streptavidin and chromogen.



Western blot - Anti-SLITRK4 antibody (ab115690)

Lane 1 : Anti-SLITRK4 antibody (ab115690) at 0.5 µg/ml
Lane 2 : Anti-SLITRK4 antibody (ab115690) at 1 µg/ml

Lane 1 : Mouse brain tissue lysate
Lane 2 : Mouse brain tissue lysate

Predicted band size : 94 kDa

References for Anti-SLITRK4 antibody (ab115690)

ab115690 has not yet been referenced specifically in any publications.

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Manufacturer's Dilemma

Fact is, the Validation cost of an antibody counts a minimum 2/3 of entire antibody cost in the case of peptide antibody production. Burden of Inventories are completely on the shoulders of manufacturers.

The dilemma that the manufacturers face is: Should the limited capital go toward validating successful antibodies or toward making more not-so-well validated antibodies which may become hot sellers?

With distributors relabeling their products, the incentives of brand loyalty are eliminated, and some manufacturers choose to sacrifice quality.

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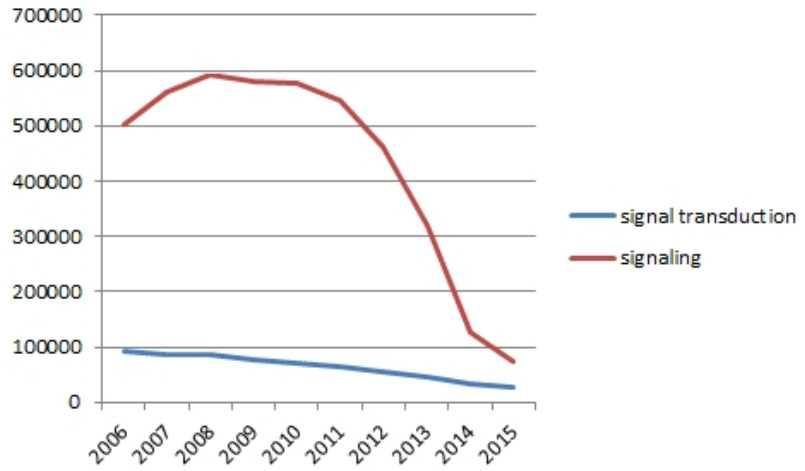

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Cost Structures of Re-brander and Manufacturers

A Re-Brander

Millions (British Pounds)	As of:	Y2011	Y2012	Y2013	Y2014	
Total Revenues		83.3	97.8	122.2	144	29.5%
Cost of Goods Sold		27.2	30.3	35.5	42.5	
Gross Profit		56	67.6	86.7	101.5	70.5%
Operating Expenses		23.8	29.9	42.2	55.4	
Operating Income		32.3	37.6	44.6	46.1	

A Manufacturer

Millions (Taiwan Dollars)	As of:	y2011	Y2012	y2013	y2014	
Total Revenue		472.6	463.8	463.7	438.1	48.9%
Cost of Goods Sold		204	208.9	227.5	214.4	
Gross Profit		268.5	254.9	236.2	223.8	51.1%
Operating Expenses		146.7	160.5	156.9	161.3	
Operating Income		121.8	94.3	79.3	62.5	

Market force #4: Capital investment, a bless and a curse

Let's be clear about something: None of the top biotech investors invested in Theranos. Five of the best-regarded biotech firms—Venrock, Third Rock Ventures, Polaris, Deerfield, Versant—either didn't meet with Theranos at all or passed on the pitch. The Silicon Valley firms with health care practices, like Google Ventures and Bessemer Venture Partners, weren't swayed, either. https://www.fastcompany.com/3059230/the-theranos-scandal-is-just-the-beginning

Hundreds of newly started small antibody companies in recent years fueled mainly by money from real estate over spill and governmental start-up funding. It is simply because the entry barrier is low so fund seeker can easily demonstrate a prototype – a rabbit in the back yard. But the market barrier is so high that some thing had to give.

Example A: a company raised 5 million USD produced 6,000 peptide generated antibodies. We randomly tested 40 of them, all failed.

Example B: Elisa Kit company – see reference on GenomeWeb - Faulty Antibodies Continue to Enter US and European Markets

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Cheating sheets for dumb money

year 1	$2,800,000	$2,800,000	$2,800,000	$2,800,000	$2,800,000	$2,800,000	$2,800,000	$2,800,000	$2,800,000	$2,800,000
year 2		$2,800,000	$2,800,000	$2,800,000	$2,800,000	$2,800,000	$2,800,000	$2,800,000	$2,800,000	$2,800,000
year 3			$2,800,000	$2,800,000	$2,800,000	$2,800,000	$2,800,000	$2,800,000	$2,800,000	$2,800,000
year 4				$2,800,000	$2,800,000	$2,800,000	$2,800,000	$2,800,000	$2,800,000	$2,800,000
year 5					$2,800,000	$2,800,000	$2,800,000	$2,800,000	$2,800,000	$2,800,000
year 6						$2,800,000	$2,800,000	$2,800,000	$2,800,000	$2,800,000
year 7							$2,800,000	$2,800,000	$2,800,000	$2,800,000
year 8								$2,800,000	$2,800,000	$2,800,000
year 9									$2,800,000	$2,800,000
year 10										$2,800,000
subtatal	$2,800,000	$5,600,000	$8,400,000	$11,200,000	$14,000,000	$16,800,000	$19,600,000	$22,400,000	$25,200,000	$28,000,000
									Total	$154,000,000

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The kids are alright

All these are just growing pain. The antibody market eventually will have a vertical integration to reach the equilibrium:

1. Either Distributors integrate manufacturing, and it is happening, or
2. The manufacturers increase their target coverage to 100% either by merging with each other or self manufacturing. It is happening too.

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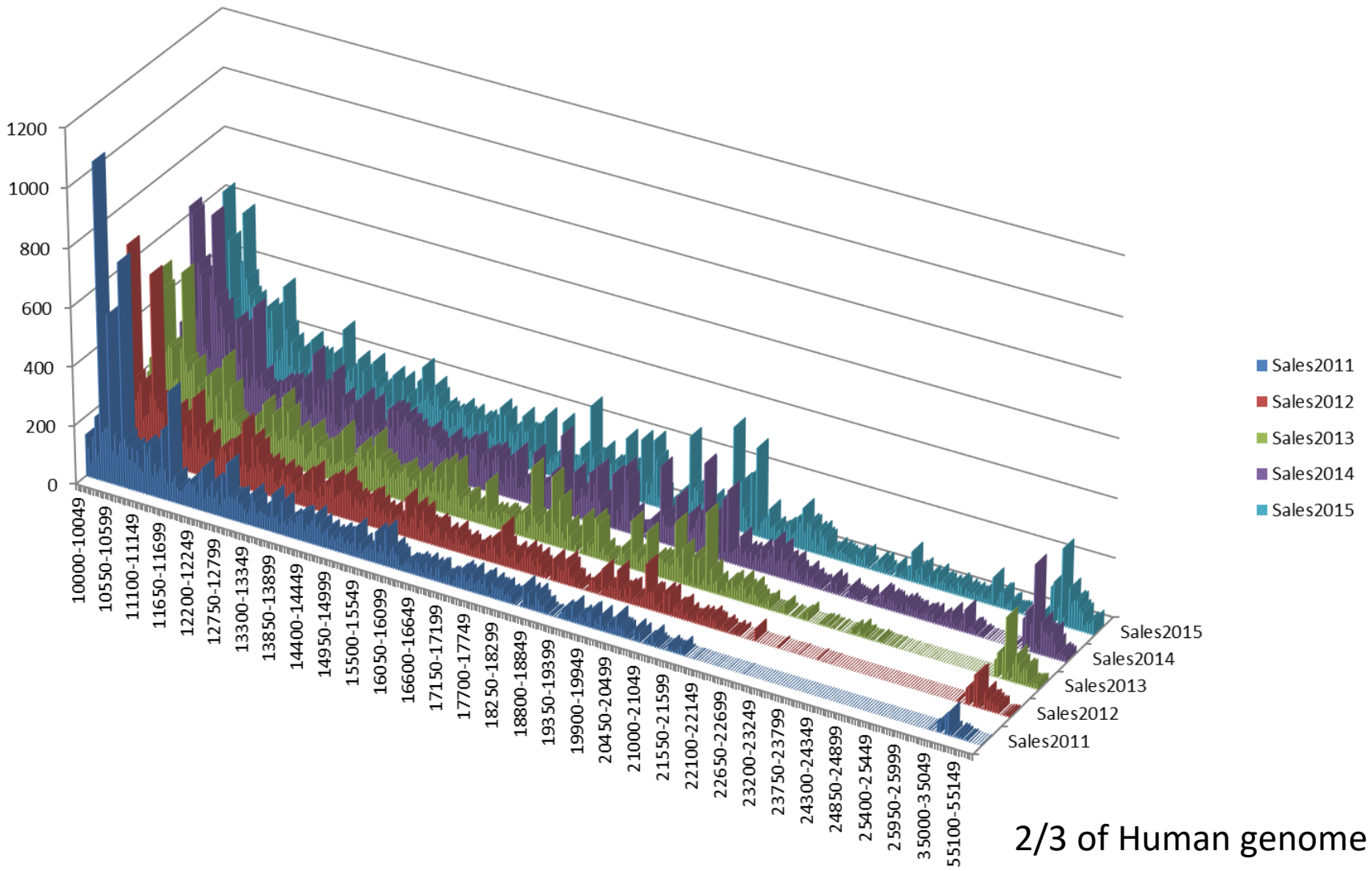

2/3 of Human genome

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What now?

-- Do what scientists always do, ask questions and transparency.

1. Know who made the antibody. This is your collaborator, not your supermarket. Have the scholarly exchange of information as you always do. Since they are an continued research, scientists of the consumer side, so be in direct communication with scientists in manufacturer sides.

2. Know your antibodies. Antibody and antibody applications are ongoing research progress. So it is a progress report. understand the how the production (like experiment) was made, and more importantly understand what further need to be done.

3. Assign the responsibilities to the antibody manufacturers, as if they are carrying a part of your experiment, rather than a faceless shadow hidden on an supermarket shelf.

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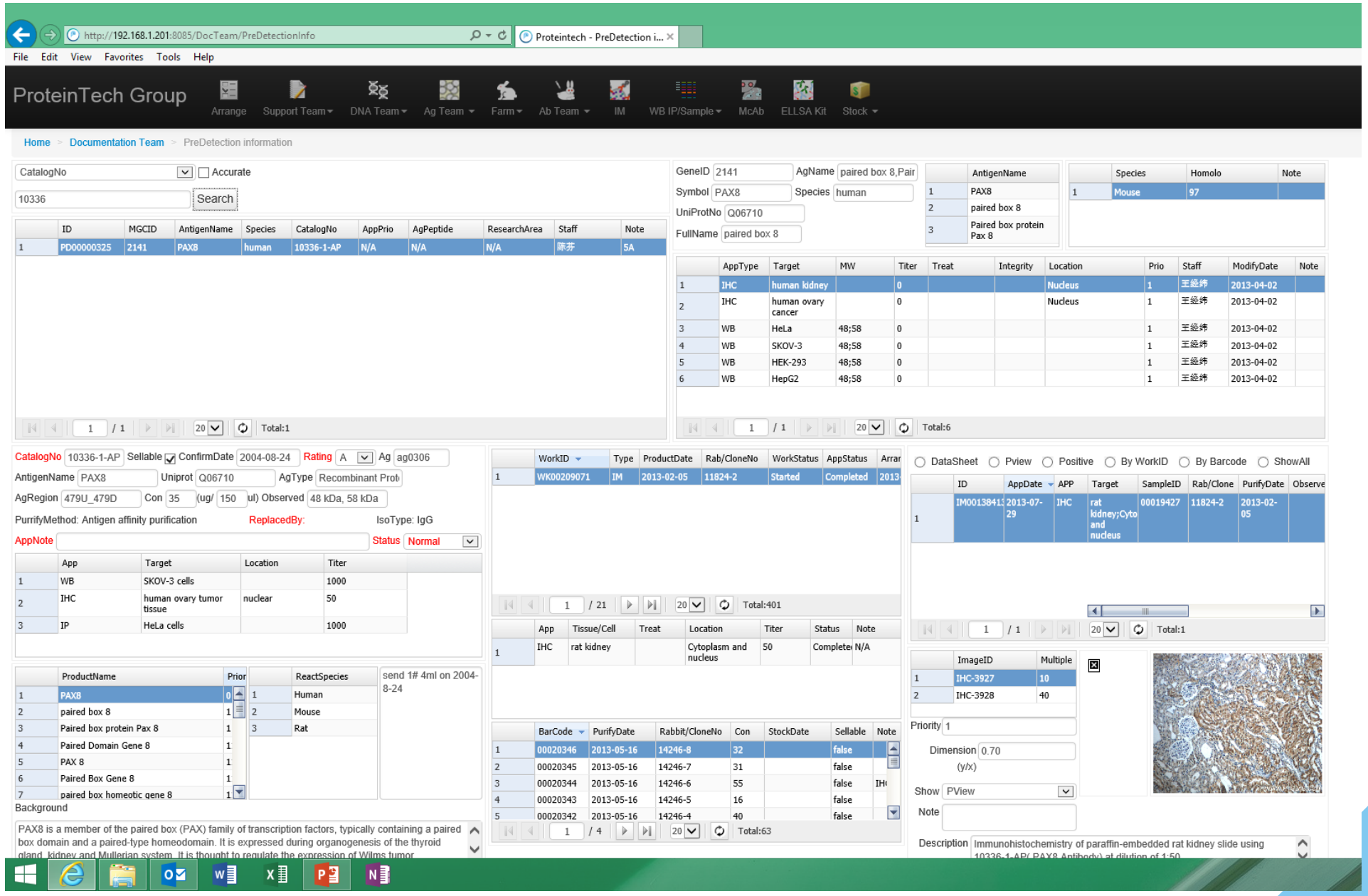
We offer the history of every antibody, from the inception to validation



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