DICKSON insights

April 2016 • CD299

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RUNNING OUT OF TIME

EXPIRING DRUG PATENTS

The Insights Feature Story

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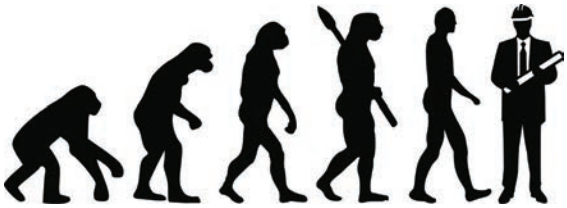

Embracing Change.

It Can Offer **Big Opportunities.**

JEFF RENOE ▪ **DICKSON INSIGHTS** EDITOR-IN-CHIEF

As we've matured as a species we've learned how to better care for ourselves so that we can live longer. Over the last one hundred years we've seen life expectancies double, triple and, in some countries, even quadruple.

From treatment, to an understanding of disease, to the medicines that prevent illness, protect us and help us recover, modern medicine has been a major driver of these gains. **To say that pharmaceuticals are a major part of this wouldn't be doing the industry an injustice. It's big business after all.**

That's why it's often important for us to pay attention to the business and watch how things are changing, because changes affect the industry and the opportunities for consumer care. New breakthroughs can mean new hope for patients who are suffering. Changes in insurance law can mean stress for both providers and consumers who are in need of care. And, one of the most important aspects from the business side can often involve the expiration of valuable drug patents.

This month, you'll find stories like this in the pages that follow, with more information often available online at blog.dicksondata.com.

Thanks for reading, and I hope you enjoy the April issue of **Dickson Insights.**

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Reader Mail

During last quarter's feature stories, we covered topics relating to humidity and its effects on the body and the workplace. Within one story we touched on the effects that mold can have on your health. Here is an excerpt from the piece.

Different people can have different reactions to inhaling air that contains mold spores. Some people suffer irritations from the fungi. Mold can cause symptoms in these people such as nasal congestion, eye irritation, wheezing, or even cause them to break out in rashes. Some people deal with serious allergies to mold which can cause a more severe reaction. This could cause fever, shortness of breath and respiratory illness. It can even trigger Asthma attacks in those with the condition. The Center for Disease Control and Prevention (CDC) has also noted that recent studies have suggested a potential link of mold exposure to young children and the development of asthma. The chronic lung disease accounts for nearly two million emergency room visits each year and kills nine Americans every day.

According to the University of Minnesota Environmental Health Sciences Division, mold is also dangerous to the body through ingestion or absorption. When we ingest the fungus on spoiled food, it affects the digestive system and can cause diarrhea, dehydration, nausea and stomach cramps. Dermal absorption is rare and occurs through skin contact. Our bodies interact with mold often in the natural environment, but through personal hygiene, we are able to remove any contamination before it becomes a problem. However, if we do not keep ourselves clean, or are unable to clean our skin surface regularly, disease could exist.

This hit close to home with one of our readers, Cindy Beckwith. She sent us a letter to share her firsthand account with high levels of moisture and how such conditions affected her body and work experiences.

Cindy offered us the chance to publish this letter because she wanted others to know that these risks are real and potentially life changing. If you're having issues that you believe may be related to mold or other inhaled fungi in your home or office, make sure to visit the doctor early before the damage potentially becomes irreversible. You can read more on the dangers of mold in our blog at **blog.dicksondata.com/2016/02/mold-and-moisture/**

Dear Editor,

Mold is a health risk that too many people take lightly. About six years ago, I worked in an office building with mold contamination. During the early spring, the building was hit by a small tornado and flooding (that caused) the structure and carpeting to become saturated. During the heat and humidity of the late spring/early summer, the windowless office I worked in began to smell musty. Others from outside noticed and the handful of girls working alongside me in the small space we shared began to complain about the smell. I began to notice chest pain and a cough while on my afternoon walks around the building. The cough, chest pain and eventual breathlessness progressed enough for me to mention it to my doctor to investigate further.

After trying an inhaler to see if it would alleviate the symptoms, (to me and my doctor's surprise it did), he began asking questions about the building I worked in. I mentioned it was probably built in the later 70's, (was) windowless and recently flooded. He suspected adult onset asthma from prolonged mold exposure and after I was examined by numerous specialists his suspicions were confirmed. I had begun to break out in hives from the mold in my office and had to eventually leave the position due to severe illness. Six years later my asthma persists though not nearly as bad. I use a daily inhaler and a rescue inhaler and probably will the rest of my life due to the prolonged exposure to mold damaging my lungs.

Sincerely,

Cindy Beckwith

The Zika Virus:
A Bite That's Worse Than The Bark

Fear. It's an emotion that humans feel in order to command a response of caution. It can happen for many reasons, but often it's the unknown that drives the feeling. Rarely is that more evident than when it comes to our health, let alone the health of our children. It's for that reason that the Zika virus has gotten the US government involved, from the CDC all the way to President Obama himself.

Beginning in May of 2015, the Pan American Health Organization (PAHO) confirmed the first Zika virus infection in Brazil. That infection led to reports of the Guillain-Barre syndrome, a condition that causes pregnant women to give birth to babies with birth defects and, at times, poor pregnancy outcomes. Since it's appearance in South America, the syndrome has spread north, out of South America and into Mexico in the North American continent. As of publishing, more than 150 cases of the virus had been diagnosed in the US.

Late last month, the World Health Organization made it known that the virus had begun "spreading explosively" throughout the Americas, and an estimated three to four million infections have occurred in the region over the last twelve months. The rapid spreading is due to its primary method of transition: The mosquito. Now, with the swift migration of the disease northward, the President is applying pressure on the CDC to expedite diagnostic tests, vaccines and therapeutic drugs. Unfortunately vaccine development typically takes years.

The 'typical' development process has several steps, from development to trials to approval and licensure. The exploratory stage that involves basic laboratory research can often take as much as two to four years and, as we discuss in this month's feature, 95% of medicines actually fail during development. There is hope, however. The Zika virus fits in the same family as several others that have already begun vaccine creation, including dengue, West Nile and chikungunya. Unfortunately, falling under the umbrella of other viruses provides no guarantees that a solution is any closer at hand, but it is likely that they offer a roadmap for developing something similar against the new threat. In fact, the Daily Mail has already reported that the US may have a number of vaccines that are ready for human trials though one likely won't be ready to go live for several years. Not to be out done, the Daily News has reported that a Canadian developer has presented an aggressive timeline that would claim to produce an antidote prior to the end of 2016. Still, neither opportunity is a guarantee that a solution is at hand.

While we're left having to wait for a solution, whether it be a cure or a preventative measure, all we can do is help protect people against developing the virus by educating them on how to care for themselves and their loved ones. Because the primary carrier method is through mosquitoes, it'll be important to take precautions in order to guard against the breeding of the bugs and to protect yourself from being bitten by mosquitoes that hatch.

Wikihow.com has compiled a great list on how to guard against breeding. Below are a few highlights.

- **Eliminate Standing Water** | Stagnant water can quickly become a mosquito breeding ground. Make sure that places where water stands are cleaned regularly, and if the water is collected purposefully make sure you replace it or use something, like a fountain, to keep the water circulating.

- **Keep lawns, bushes and weeds neatly trimmed and well maintained** | This is more for keeping the mosquitos away than breeding new ones. Tall grass and full shrubbery provides locations for the insects to rest and hide from other predators.

- **Eliminate or fill nooks, crannies and holes** | These are locations that can harbor mosquitoes so that they can lay their eggs. If you can't remove them from patios, trees or your yard, consider filling them with sand.

The CDC has also put together a number of pointers for keeping yourself from being bitten. Again, here are a few highlights.

- **Wear insect repellent** | According to the CDC such chemicals are safe and, when used as directed, they are the best way to protect yourself and those around you from getting bitten.

- **Cover Up** | It's tough to think about in the hot summer months, but, weather permitting, cover up with long sleeved shirts and pants and keep your skin covered and reduce risk.

- **Keep bugs outside** | If air conditioning isn't an option make sure that all windows and doors have screens that are in good shape and will keep the bugs out of your home.

Even though there is no way to guarantee personal safety, these tips can help reduce your risk. If you do happen to contract the illness, the most common symptoms include fever, rash, joint pain or conjunctivitis. Also, make sure to avoid being bitten if you are infected to reduce the spreading of the syndrome. The CDC has also made additional suggestions and information available for women who are pregnant.

Caution is always something that should be shown when a new illness appears, especially when it is one we are ill prepared to face. However, as we educate ourselves and continue to learn about the virus we can work together to reduce risk and limit its ability to spread. Then, hopefully, we can all learn to face it without fear.

D

DicksonOne

Wireless Temperature and Humidity Monitoring

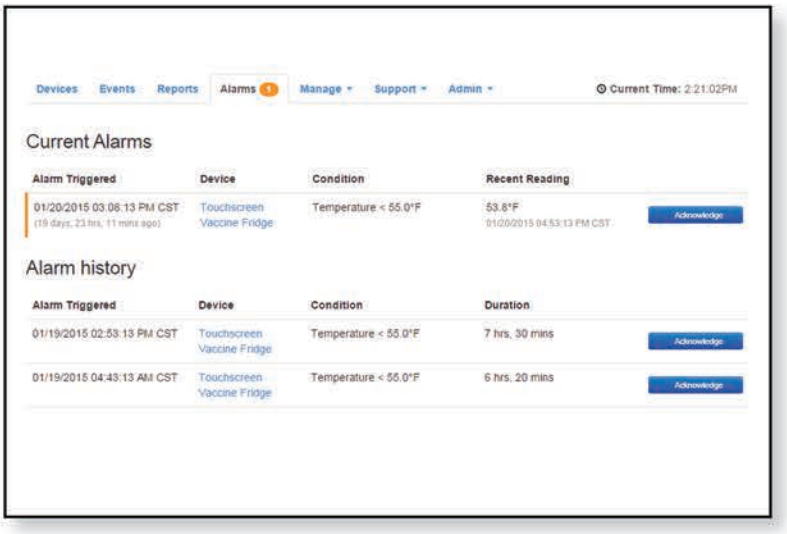
HOW IT **WORKS**

When you log onto **DicksonOne.com**, your environmental data, from every location, appears before your eyes. Charts and pens, get outta here. USB cords and software on a disc, you too. **DicksonOne** Loggers transmit your data wirelessly to the **DicksonOne** Cloud, where you can access it anytime.

Power Over Your Environment

EMAIL, TEXT & PHONE CALL ALARMS

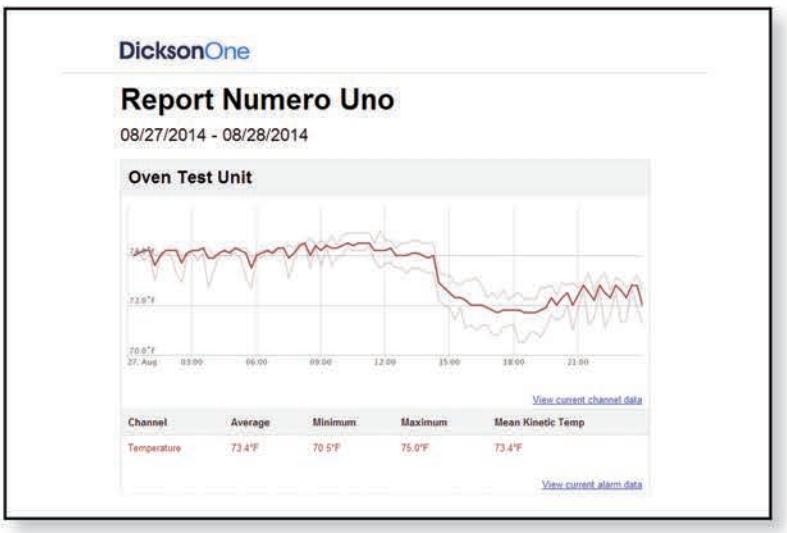
When something bad happens in your facility, **DicksonOne** can send anyone in your organization an email, text, or phone call. Temperature too high? Humidity too low? We've got you covered.



CUSTOMIZABLE REPORTS

The DicksonOne Reporting Suite allows you to:

- Create and customize reports for any and all of your loggers
- Choose who in your organization will receive which reports
- Change and modify the frequency of reports



TEMPERATURE MAPPING SERVICES

KEEPING YOUR PRODUCTS SAFE

HOW IT **WORKS:**

WHAT **YOU GET:**

- Warehouse Mapping
- Problem Spot Analysis
- Refrigerator, Freezer, and Incubator Mapping
- Control System Analysis
- Acceptance Criteria Creation
- Temperature Recovery Studies
- Self-Mapping Kits
- Temperature and Humidity Monitoring Consultation

WHAT **WE OFFER:**

- 90 Years of Temperature Mapping Experience
- A team of expert Consultants, Engineers, and Mapping Technicians
- 21CFR11 Compliance
- High Accuracy, High Reliability Data Loggers
- A2LA Calibrated Temperature Recorders
- Secure Data Recovery, Analysis, and Distribution

Meet The New

DicksonOne Logger

THE BEST JUST GOT BETTER

Larger, More Detailed Display ▪ Compatible with New Universal Replaceable Sensors

Over the Air Updates ▪ Smaller Footprint

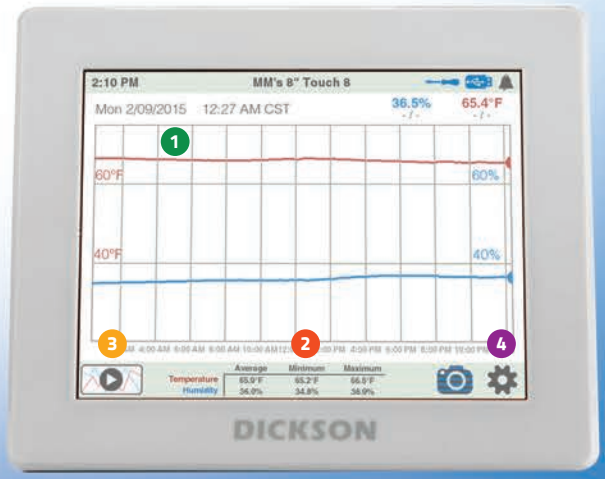
Updated Design

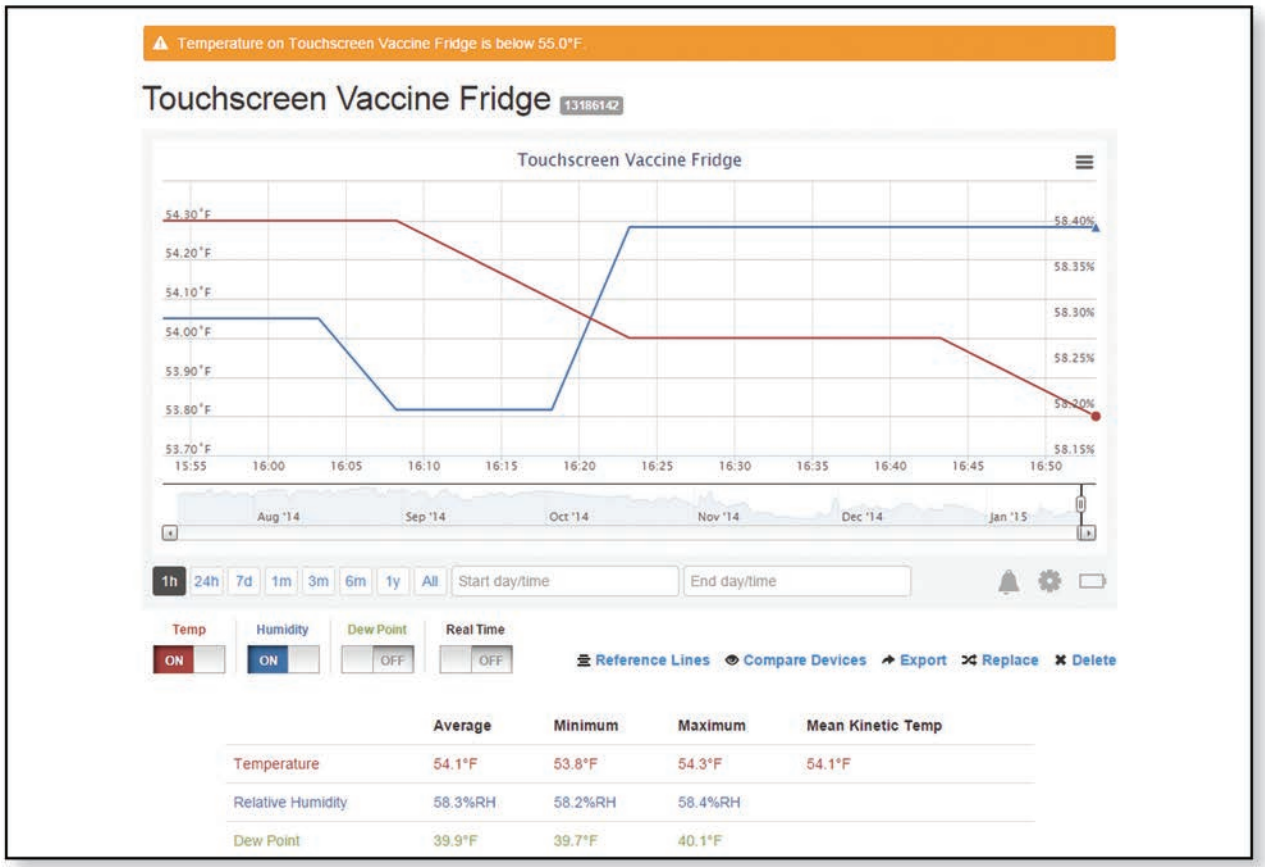
DicksonOne **Touchscreen Loggers**

Our goal when designing the new line of **Touchscreen Data Loggers** was to create a feature-heavy and easy-to-use device that allowed users access to their entire data history, anywhere. We pushed the limits of connectivity, user-interface, and functionality, to deliver the most robust data logger on the market.

Data At The Source

1. **The Graph** Your environmental history just got a whole lot easier to navigate through. We overhauled the user-interface, and made it easy to view and manage your data.
2. **Your Channels** Every touchscreen will automatically calculate the minimum, maximum, and average temperatures of your selected view.
3. **Real-time Monitoring** Push the play button, and your device will update back to the most recent set of readings.
4. **Device Settings** Your Touchscreen is robust. When you navigate your devices settings, you can adjust sample rates, set alarms, and connect to DicksonOne.





NOW WITH **DicksonOne**

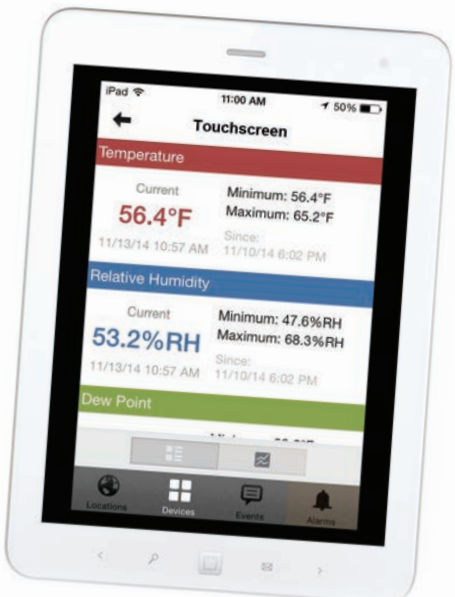
The **Touchscreen** now gives you the option to connect directly to **DicksonOne.** You get all of your data at your fingertips, and now you can access it anywhere too. Just connect your device to your local WiFi network or plug it into an Ethernet port, log into **DicksonOne**, and boom, complete data control.

DicksonOne Allows You To:

- Get email, text, or phone call alarms from your Touchscreens.
- Access every one of your Touchscreens' data history on one website.
- Generate customizable reports, delivered directly to your inbox when you want.

The new Touchscreen allows for USB download to DicksonWare.

Only DicksonWare A017/A027 will function with Touchscreen Loggers.



DicksonOne
Touchscreen

MODEL	REMOTE PROBE
TSB	USB Download
TWE	DicksonOne WiFi/Ethernet Connection and Download
TWP	DicksonOne Download and Power over Ethernet

The TSB, TWE, and TWP all allow for basic USB download independent of DicksonOne. Use DicksonWare A017/A027 for USB download with these models.

DicksonOne
Display Logger

MODEL	REMOTE PROBE
DWE	DicksonOne WiFi / Ethernet Connection and Download

DicksonOne
Software

DEVICES	FEATURES
1 to 10	Unlimited Data, Multiple Sample Rates, API Access, Email, Phone, and Text Alarms
11 to 25	Unlimited Data, Multiple Sample Rates, API Access, Email, Phone, and Text Alarms
26 to 50	Unlimited Data, Multiple Sample Rates, API Access, Email, Phone, and Text Alarms
51 +	Unlimited Data, Multiple Sample Rates, API Access, Email, Phone, and Text Alarms

* Dickson offers a Basic Plan with a rolling window of 30 Days of data. One hour sample rates for unlimited loggers at no cost.

Calibration In Five Seconds

HOW REPLACEABLE SENSORS **WORK**

Dickson Replaceable Sensors are Dickson's answer to the headache of calibrating your temperature or humidity monitoring device. When your device needs to be calibrated, just pop off your sensor and pop on a new one. It's that easy. Now when you order a DicksonOne or Touchscreen Logger, you get the benefit of never having to ship a logger back to us again.

WITHOUT REPLACEABLE SENSORS

1. Order a recalibration for your device
2. Acquire a Return Authorization Code from a Dickson Representative
3. Take unit out of its environment
4. Move products out of environment/install backup monitoring system
5. Box unit up
6. Ship unit to Dickson
7. Dickson recalibrates unit and ships it back
8. Receive the unit
9. Disassemble backup system/move product back into environment
10. Reinstall unit/system

Total Down Time: 7-10 Days

VS

WITH REPLACEABLE SENSORS

1. Order a Replaceable Sensor
2. Take old sensor off, put new sensor on

Total Down Time: 0 Days

All DicksonOne and Touchscreen Loggers are

RS COMPATIBLE.

High Temp Solutions

D605 Probe sold separately. For more information on Dickson's Probes and Accessories, visit **dicksondata.com.**

1. **HT 300 Waterproof, High Temperature Data Logger** HACCP and FDA Compliant. USB Download. IP68 Rating. Temperature Range -40° to 257°F (-40° to 125°C).
2. **HT350 High Temperature Process Logger** HACCP Compliant, K-Thermocouple Probe, USB Download, and a large temperature range. Temperature Range -40° to 257°F (-40° to 125°C).

Instant Data Solutions

3. **TC700/TH700 Touchscreen Handheld Indicator** Instant temperature or temperature/humidity data. No-slip silicone cover. Battery powered.
4. **RL200 Report Logger** We decided to make the best compact data logger on the market, our RL200. With a new outer case, user selectable logging times, and redesigned PC interface, it's exactly what you need.

Temperature and Temperature/Humidity

Chart Recorders

Want a physical readout right where you are monitoring? Our Chart Recorders have you covered. For ninety years we've built the best chart recorders in the business. Check out our models below.

8 and 6 Inch Models

Eight and Six Inch Chart Recorders display detailed temperature and humidity values.

MODELS AND FEATURES

KT6P	6 Inch Temperature
KT8P	8 Inch Temperature
TH6P	6 Inch Temperature and Humidity
TH8P	8 Inch Temperature and Humidity

4 and 3 Inch Models

Four and Three Inch Temperature Chart Recorders designed to fit any application.

MODELS AND FEATURES

SL4350	4 Inch
SL4100	4 Inch
SC3 Series	3 Inch

Charts sold separately. For charts and accessories, call **630.543.3747** or go to **www.DicksonData.com.**

PRESSURE DATA LOGGERS

Pressure Data Logger One second sampling rate. User replaceable battery. Optional delayed start. USB connectivity. Pressure sensor includes built-in diaphragm seal.

PR125	0-100 PSI
PR325	0-300 PSI
PR525	0-500 PSI

Rugged Utility Pressure Data Logger Water resistant case. 3 year battery. Unobtrusive design. Fits easily in a toolbox. USB Connection.

PR150	0-100 PSI
PR350	0-300 PSI

PRESSURE CHART RECORDERS

4 and 8 Inch Models

Four and Eight Inch Chart Recorders to meet your needs.

Single AA battery powered. Rugged low-maintenance design features. 7-day or 24-hour recording times. 1/4 inch NPT Connector.

MODELS AND FEATURES

0-100 PSI	**PW860/1**	**PW470**
0-200 PSI	**PW864/5**	**PW474**
0-300 PSI	**PW866/7**	**PW476**
0-500 PSI		**PW479**
0-1000 PSI	**PW875**	

Charts sold separately. For charts and accessories, call **630.543.3747** or go to **www.DicksonData.com.**

MAPPING DATA LOGGERS

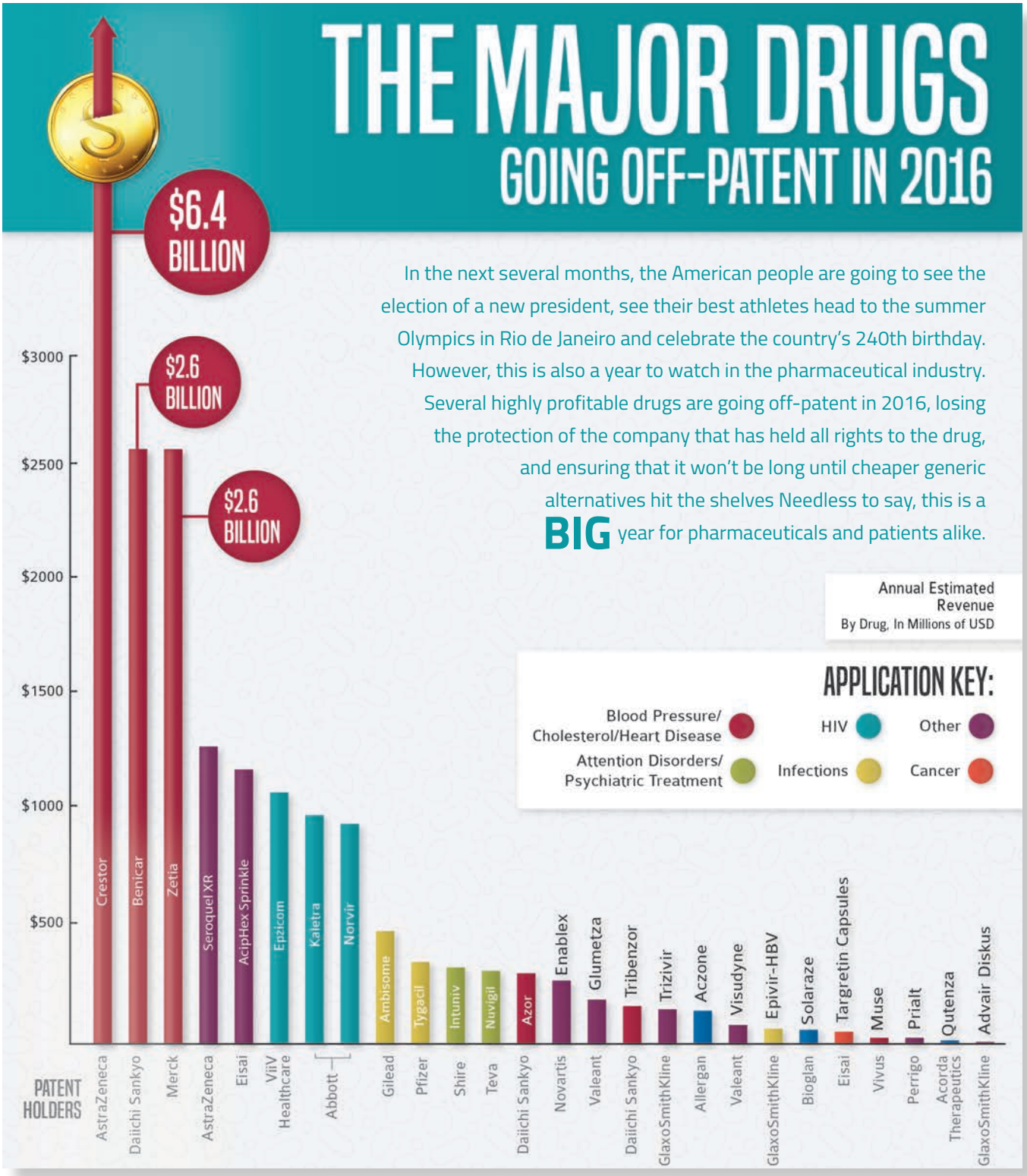
SP125 Temperature Logger. Accuracy ±1.2°F, ±0.67°C. Range -10 to 176°F, -23 to 80°C.
SP175 Temperature Logger with Thermocouple Probe. Accuracy ±1.8°F, ±0.1°C. Range -300 to 2000°F, -30 to 50°C. A203 Probe required for +500°F.
TP125 Temperature and Humidity Logger. Accuracy ±0.8°F, ±0.45°C. Range -10 to 176°F, -23 to 80°C.

SK550 Temperature. Pack of twelve. Accuracy ±1.8°F, ±1°C. Range -4 to 158°F, -20 to 70°C.
TK550 Temperature & Humidity. Pack of twelve. Accuracy ±1.8°F, ±1°C. Ranges -4 to +158°F, -20 to +70°C.

DISPLAY DATA LOGGERS

SM300 Temperature Logger. Range -4 to 158°F, -20 to 70°C. Accuracy ±0.8°F, ±0.44°C.
SM320* Temperature Logger. Remote Probe. Range with Probe -300 to 2000°F, -184 to 1093°C. Accuracy ±1.8°F, ±1.0°C.
SM325* Temperature Logger. Two Remote Probes. Range with Probe -300 to 2000°F, -184 to 1093°C. Accuracy ±1.8°F, ±1.0°C.
SM420 Temperature Logger. Remote Probe. Range with Probe -50 to 350°F, -45 to 176°C. Accuracy ±0.5°F, ±0.28°C.
TM320 Temperature and Humidity Logger. Range -4 to 158°F, -20 to 70°C. Accuracy ±0.8°F.
TM325 Temperature and Humidity Logger. Remote Probe. Range -40 to 185°F, -40 to 85°C. Accuracy ±0.8°F.

SP425 Temperature Logger. Digital Display. Accuracy ±1.2°F, ±0.67°C. Range -4 to 158°F, -20 to 70°C.
TP425 Temperature and Humidity Logger. Digital Display. Accuracy ±0.8°F, ±0.45°C. Range -4 to 158°F, -20 to 70°C.


THE MAJOR DRUGS
GOING OFF-PATENT IN 2016
$6.4 BILLION
$2.6 BILLION
$2.6 BILLION
In the next several months, the American people are going to see the election of a new president, see their best athletes head to the summer Olympics in Rio de Janeiro and celebrate the country's 240th birthday. However, this is also a year to watch in the pharmaceutical industry. Several highly profitable drugs are going off-patent in 2016, losing the protection of the company that has held all rights to the drug, and ensuring that it won't be long until cheaper generic alternatives hit the shelves Needless to say, this is a BIG year for pharmaceuticals and patients alike.
Annual Estimated Revenue
By Drug, In Millions of USD
APPLICATION KEY:
Blood Pressure/ Cholesterol/Heart Disease
HIV
Other
Attention Disorders/ Psychiatric Treatment
Infections
Cancer
$3000
$2500
$2000
$1500
$1000
$500
PATENT HOLDERS
Crestor
AstraZeneca
Benicar
Daiichi Sankyo
Zetia
Merck
Seroquel XR
AstraZeneca
AciphHex Sprinkle
Eisai
Epzicom
ViiV Healthcare
Kaletra
Abbott
Norvir
Abbott
Ambisome
Gilead
Tygacil
Pfizer
Intuniv
Shire
Nuvigil
Teva
Azor
Daiichi Sankyo
Enablex
Novartis
Glumetza
Valeant
Tribenzor
Daiichi Sankyo
Trizivir
GlaxoSmithKline
Aczone
Allergan
Visudyne
Valeant
Epivir-HBV
GlaxoSmithKline
Solaraze
Bioglan
Targretin Capsules
Eisai
Muse
Vivus
Prialt
Perrigo
Qutenza
Acorda Therapeutics
Advair Diskus
GlaxoSmithKline

Expiring Drug Patents:
Cheaper Generics Will Hit Shelves

What exactly does going off-patent mean? When a pharmaceutical company develops and "brands" a drug, it's held under patent protection. Only the pharmaceutical company that holds the patent is allowed to manufacture, market and sell the drug. Patents in the United States usually run about 20 years, but patents are applied for well before the clinical trial begins, so the shelf life of a patent in the United States usually is about seven to 12 years.

What Does it Take to Get a Patent in the World of Pharmaceuticals?

The FDA publishes a tremendous amount of information on Investigational New Drug (IND) applications for new drugs. It's a process that requires paperwork, approvals, exemptions and more. Currently, federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. Because sponsors will most likely be shipping investigational drugs to clinical investigators in many states, it must seek exemption from the requirement. Here's an excerpt from the FDA's website.

"During a new drug's early preclinical development, the sponsor's primary goal is to determine if the product is reasonably safe for initial use in humans, and if the compound exhibits pharmacological activity that justifies commercial development. When a product is identified as a viable candidate for further development, the sponsor then focuses on collecting the data and information necessary to establish that the product will not expose humans to unreasonable risks when used in limited, early-stage clinical studies."

Once the drug is ready for human testing, the FDA steps in to begin its role and the process moves forward in one of any number of directions depending on the type of drug that's being patented.

1. Investigator IND | This drug is submitted by a physician who both initiates and conducts the investigation on the drug and under whose direction the drug would be administered or dispensed.

2. Emergency Use IND | This is for use with an experimental drug in an emergency situation that does not allow time for submission of an IND in accordance with an number of guidelines. It is also used for patients who do not meet the criteria of an existing study protocol or if an approved study protocol does not exist.

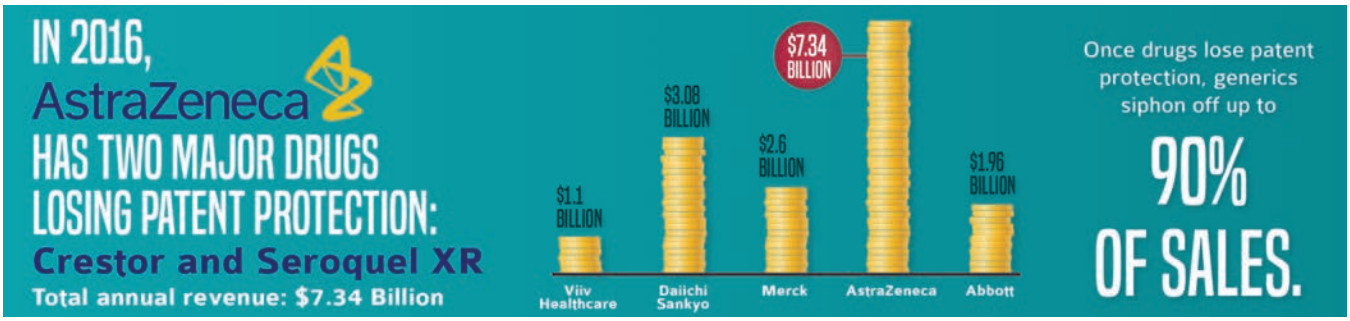
3. Treatment IND | This is used when an application is submitted for experimental drugs that show promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and the FDA review takes place.

It's important to note that there are two IND categories, Commercial and Research (non-commercial), and that they must contain information in three broad areas.

1. Animal Pharmacology and Toxicology Studies | Preclinical data must be included in order to permit an assessment as to whether the product is reasonably safe for human testing. Information on drug results on humans from foreign use is also relevant for this section.

2. Manufacturing Information | Information pertaining to the composition, manufacturer, stability and controls used for manufacturing the drug substance and the drug product must be provided in the application. This information is assessed to ensure the company can meet the necessary supply needed for consumer demand.

3. Clinical Protocols and Investigator Information | Detailed protocols for proposed clinical studies must have been considered for the FDA to assess whether the initial-phase trials will expose subjects to unnecessary risk. It must also include information on the qualifications of clinical investigators to assess whether they are qualified to fulfill their clinical duties. The application must show that a commitment will be made to obtaining informed consent from the research subjects, obtain review of the study by an instructional review board and adhere to IND regulations.



Once submitted, the sponsor must wait 30 calendar days before initiating any clinical trials. During this time the FDA can review the IND for safety to assure that those involved in human testing will not be subjected to unnecessary and unreasonable risk.

What Happens When Patents Expire?

Manufacturers desiring to sell the now-generic version of a drug that has gone off-patent do not need to prove the safety and efficacy of the drug since that has already been done. Instead, they submit a New Drug Application (ANDA) to the Food and Drug Administration (FDA) intended to demonstrate that the proposed generic is the same as the previously approved drug. While it is commonly believed that the FDA's drug approval process is slower than its foreign competitors, it is often faster and more willing to approve certain drugs. Seventy-five percent of the new drugs approved by both the FDA and European Medicines Agency (EMA) between 2006 and 2010 were first approved in the United States, while the FDA approved 32 of 35 prospective cancer drugs from 2003-2010. The EMA approved only 26.

What's at Stake?

At Dickson, we're all about data, and when it comes to intellectual property in the pharmaceutical industry, the numbers are staggering.

- Estimates vary on how much it costs to bring a new drug to market, but a recent study from the Tufts Center for the Study of Drug Development (CSDD) pegs the average total at $2.9 billion. However, 95 percent of medicines fail during development, and only two in 10 recoup their research and development costs.
- Once drugs lose patent protection, generics siphon off up to 90 percent of sales.
- The average annual savings from switching to generic medications is estimated to be $420 per consumer.

Because of the high cost of research and development, pharmaceutical companies advocate for strong patent protection to extend the exclusivity of their drugs. The US is an outlier on this, however, and patent duration came under scrutiny during the recent Trans Pacific Partnership (TPP) negotiations last July. According to Judit Rius Sanjuan in a piece by the New York Times, "The goal of the pharmaceutical industry is to change the rules internationally, to change global norms with a new monopoly that is cheaper for the companies and stronger."

United States law protects data collected during the development of biologic medicines for 12 years, allowing drug makers to recoup their research and development investments before generic companies can come in with far cheaper versions. Other countries that were involved in the TPP negotiations had windows of eight years or less, with Australia digging a line in the sand at five. According to Australia's trade and investment minister, Andrew Robb, they've mandated the five year protection because "it takes six or seven years" for generic-drug makers to develop what are known as biosimilars. Activists actually want the window closed all together in order to force major brands to compete with generics to keep prices down. Observers believe that the most likely course of action will be for the 12 year protection provided by US law to be reduced to the five to seven year window that's in place in other countries around the world. It would be a move that would leave both sides, the pharmaceutical manufacturers and the activists, unfulfilled.

Who Stands to Lose Out?

AstraZeneca is one company in 2016 that is losing two major drugs from patent protection—Crestor and Seroquel XR—worth a combined annual revenue of $7.34 billion. The top five biggest patent losses in 2016 per holder after AstraZeneca are Daiichi Sankyo, Merck, Abbott and ViiV.

Of course, there's room here for consumers to gain. Four major HIV drugs also are going off-patent in 2016: Epzicom, Trizivir, Norvir and Kaletra, with a current cost-per-pill at $39.57, $11.07, $8.83 and $7.22, respectively. The good news? Costs for generics are 80 to 85% lower on average than those of patented drugs. It'll make 2016 a big year for consumers who are in need of such medication.

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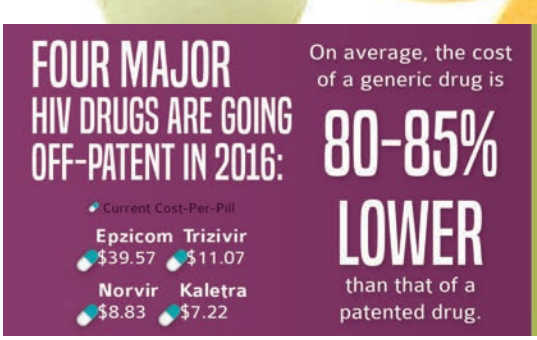

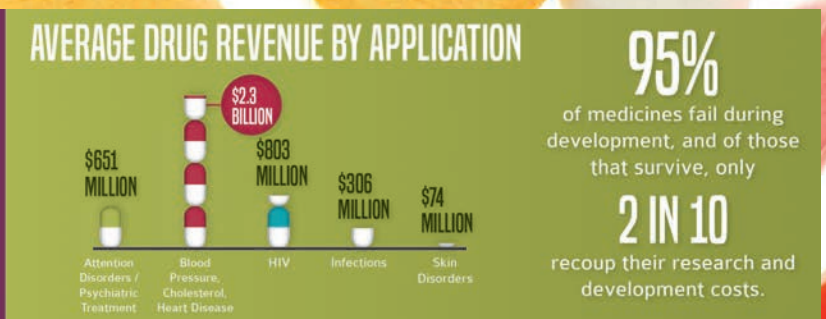

DICKSON
930 South Westwood Avenue
Addison, Illinois 60101-4917

PHONE **800.323.2448**
FAX **800.676.0498**
www.DicksonData.com

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