

The Next Generation of Patent Expirations

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Contributing Writer

With the world population soon to top 7 billion, we have more than 1 billion people who have very little food security and do not know where their next meal will come from – that’s more than the population of North America and Europe combined. Global food supply and global peace are interlinked. Agrochemicals play a small part in the cost of food production and other factors such as food wastage. Other inputs such as fertilizers and machinery and delivery infrastructure are all contributors. Nevertheless, during the last 60 years agrochemicals have made significant contributions to improving yields and will continue to underpin food security and contribute to global peace.

There will inevitably be greater use of agrochemicals and greater need to deliver safe, innovative products to increase yields and counter resistance problems in a cost-effective way. This will be more important than ever. There must be a balance between the innovator companies reaping the rewards for providing new products and a healthy, generic sector that contributes to driving the cost of pesticides down.

In 2013, the agrochemical crop protection industry was worth more than \$50 billion at the distributor level, and it is forecast to continue to grow at 6% to 8% per year over the next three to five years. There are approximately 500 active ingredients (AIs) manufactured from organic synthesis that account for more than 90% of the total market. As a result of mixture products containing more than one AI and different types of formulations containing a variety of formulation additives – for example adjuvants and surfactants – there are many thousands of products available to the farmer. Intellectual Property Rights (IPR) in the form of patents and data protection for registrations are fundamentally important to the dynamics of the agrochemical industry and dictate the balance between the R&D sector (innovator companies) and the generic sector. These mixture products and new formulations can also be granted patent protection and have resulted in significant segmentation of the market and protection from generic competition.

During the last 15 years agrochemical innovation has declined, and now only four to eight new AIs

are introduced into the market each year. As a result, only about 25% of the total market is accounted for by proprietary patented AIs. The generic sector (where no IPR exists) accounts for 25% to 30% of the total market, leaving 45% to 50% that is defined as the proprietary off-patent sector.

This sector can be further defined by products that:

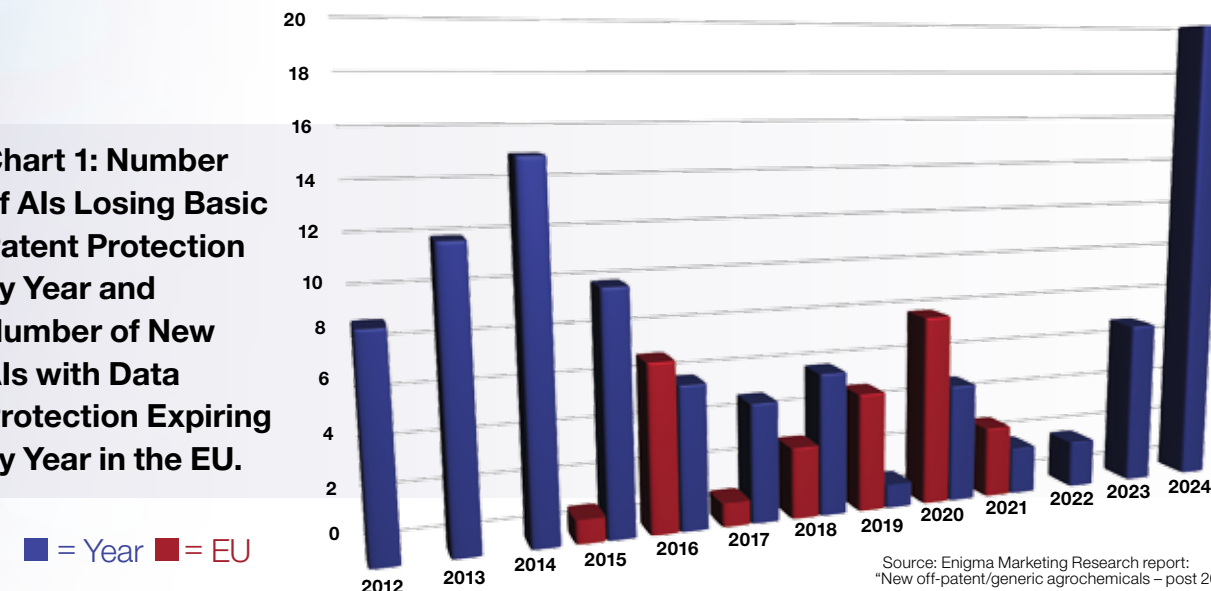
- Include a primary AI that is off-patent
- Have some proprietary technology (such as a new delivery

Table 1: AIs Losing Patent Protection 2014-2020

ACTIVE INGREDIENT	ACTIVITY	INVENTOR COMPANY
Amisulbrom	Fungicide	Nissan Chemical Industry
Benthiavalicarb	Fungicide	Kumiai Chemical Industry
Cyflufenamid	Fungicide	Nippon Soda
Cyprosulfamida	Safener	Bayer CropScience
Fenpyrazamine	Fungicide	Sumitomo Chemical Co.
Fentrazamide	Herbicide	Bayer CropScience
Flubendiamide	Insecticide	Nihon Nohyaku
Flucetosulfuron	Herbicide	LG Life Sciences
Fluopicolide	Fungicide	Bayer CropScience
Fluoxastrobin	Fungicide	Bayer CropScience
Foramsulfuron	Herbicide	Bayer CropScience
Metalaxyl-M	Fungicide	Syngenta
Metamifop	Herbicide	Dongbu Hannong Chemical
Metofluthrin	Insecticide	Sumitomo Chemical Co.
Metrafenone	Fungicide	BASF
Orthosulfamuron	Herbicide	ISAGRO
Penoxsulam	Herbicide	Dow AgroSciences
Penthiopyrad	Fungicide	Mitsui Chemical Agro Inc.
Pinoxaden	Herbicide	Syngenta
Prothioconazole	Fungicide	Bayer CropScience
Pyraclostrobin	Fungicide	BASF
Pyridalyl	Insecticide	Sumitomo Chemical Co.
Pyrifluquinazon	Insecticide	Nihon Nohyaku
Spirotetramat	Insecticide	Bayer CropScience
Tembotrione	Herbicide	Bayer CropScience
Thiencarbazone	Herbicide	Bayer CropScience
Topramezone	Herbicide	BASF
Valifenalate	Fungicide	ISAGRO

Source: Enigma Marketing Research report: "New off-patent/generic agrochemicals – post 2015"

Chart 1: Number of AIs Losing Basic Patent Protection by Year and Number of New AIs with Data Protection Expiring by Year in the EU.



Source: Enigma Marketing Research report: "New off-patent/generic agrochemicals – post 2015"

ACTIVE SUBSTANCE	COMPANY	EU PATENT EXPIRY YEAR	SPC - MAXIMUM EXPIRY YEAR	
Foramsulfuron	Bayer Crop-Science	2015	2016	<ul style="list-style-type: none"> • Foramsulfuron is a foliar, post-emergence, sulfonyleurea herbicide discovered and developed by AgrEvo (now Bayer CropScience) • EP and US patents to the basic AI expire 2015 and 2016 respectively • Main markets: Extensive geographical spread • Main crops: corn/maize and turf • Main mixture products: isoxadifen-ethyl + iodosulfuron-methyl-sodium and thiencarbazone + cyprosulfamida
Pyraclostrobin	BASF	2015	2016	<ul style="list-style-type: none"> • Pyraclostrobin is a broad-spectrum, strobilurin fungicide discovered and developed by BASF • EP and US patents to the basic AI expire 2015 • Main markets: Extensive geographical spread • Main crops: barley, cereals, citrus, corn/maize, cotton, grapes, nuts, oats, peanuts, soybeans, sunflower, vegetables and wheat • Many mixture products
Pyridalyl	Sumitomo Chemical	2015	2020	<ul style="list-style-type: none"> • Pyridalyl is an insecticide discovered and developed by Sumitomo Chemicals • EP and US patents to the basic AI expire 2015 • Main markets: China, India, Japan, Netherlands, South Africa, South Korea and United States • Main crops: cotton, ornamentals and vegetables • No mixture products
Prothioconazole	Bayer Crop-Science	2015	2019	<ul style="list-style-type: none"> • Prothioconazole is a triazolinthione fungicide discovered and developed by Bayer CropScience • EP and US patents to the basic AI expire 2015 • Main markets: Extensive geographical spread • Main crops: barley, canola, cereals, corn/maize, peanuts, rice, rye, soybeans, sugar beet and wheat • Many mixture products
Cyflufenamid	Nippon Soda	2015	2020	<ul style="list-style-type: none"> • Cyflufenamid is an amidoxine fungicide discovered and developed by Nippon Soda • EP and US patents to the basic AI expire 2015 • Main markets: EU, also Australia, Morocco, South Korea and US • Main crops: cereals, fruit, vegetables, grapevines, turf and ornamentals • Mixture products with triflumizole, difenoconazole and hexaconazole

- system, surfactant or safener, or is linked to GMO crops)
- Are mixtures containing at least one patented AI
- Have data protection issues restricting generic competition

Table 1 (p. 8) lists the 28 AIs slated to lose patent protection from 2014 through 2020, and Chart 1 (p. 9) illustrates the number of AIs that will lose patent protection in a given calendar year.

Basic Protection and SPCs

In 2015, seven of the profiled AIs lose basic patent protection, but will generic companies be successful in entering the market? Or, as we have emphasized in previous articles, will secondary patents, patent term extensions and data protection restrict the generic sector or indeed eliminate it from the market for a number of years still to come? Five of these AIs are marketed in Europe,

and as such, they have had patent terms extended as a result of Supplementary Protection Certificates (SPC) being granted (see Table 2). (See “How to Bridge the Knowledge Gap” for a more in-depth explanation on SPCs as well as Uttley’s other articles on data protection, how to analyze market demand and more at www.farmchemicalsinternational.com).

In addition to the AI patent, other patents such as process and mixture patents may exist. Prothioconazole and its mixture products were discussed in the March *FCI* article, which concluded that over 80% of the EU market for prothioconazole is for mixture products, and thus, generic entrants will find it very difficult to take significant market share for a number of years still to come.

Pyraclostrobin is a broad-spectrum, strobilurin fungicide discovered and developed by BASF. It is active against a broad range of pathogens on cereals, peanuts, grapevines, vegetables, bananas, citrus, soybeans, cotton, sugar beet, sunflowers and turfgrass.

It is mixed with many other active ingredients including:

- epoxiconazole
- boscalid
- metiram
- tebuconazole
- thiophante-methyl
- fipronil
- folpet
- triticonazole
- dimethomorph
- fenpropimorph
- triticonazole + metalaxyl
- kresoxim-methyl
- metconazole
- fluxapyroxad
- mancozeb
- thiophanate-methyl
- dithianon

SPCs exist for a number of these mixtures, extending patent protection well beyond 2015, including:

- boscalid + epoxiconazole
- dimethomorph
- epoxiconazole
- fenpropimorph
- folpet
- metiram

Data protection can be as significant as patent protection in restricting generic competition. Chart 1 (p. 9) shows the number of new AIs with data protection expiring by year in the EU.

All the AIs profiled in our latest report are classed as new AIs under Directive 91/414 and, as such, received a 10-year data-protection period. For many of these, the data-protection period extends well beyond patent expiry.

Table 3 shows the number of additional years data protection extends for some AIs whose basic patents expire in the next six years.

As the examples of prothioconazole and pyraclostrobin demonstrate, it is not sufficient just to determine when the patent for the AI expires, it is essential that would-be generic suppliers assess any extended IPR for mixture products, process patents, data protection and many other aspects before attempting to enter the market. ☺

Dr. Nigel Uttley is founder and CEO of Enigma Marketing Research. His AgriBase database and Reports help analyze new market opportunities for post-patent companies. EMR has just published the eighth report, “New off-patent/generic agrochemicals – post 2015”, which profiles 28 AIs that will lose patent protection between now and 2020. Uttley can be reached at nigel.uttley@enigmamarketingresearch.com and a sample AgriBase can be demonstrated at www.enigmamarketingresearch.com

Table 2: Patent Extensions Provided by SPCs

ACTIVE SUBSTANCE	COMPANY	EU PATENT EXPIRY YEAR	SPC - MAXIMUM EXPIRY YEAR
Foramsulfuron	Bayer CropScience	2015	2016
Pyraclostrobin	BASF	2015	2016
Pyridalyl	Sumitomo Chemical	2015	2020
Prothioconazole	Bayer CropScience	2015	2019
Cyflufenamid	Nippon Soda	2015	2020

Source: Enigma Marketing Research report: “New off-patent/generic agrochemicals – post 2015”

Table 3: Number of Years of Data Protection Extended Beyond Basic Patent Expiry

Active Ingredient	Additional number of years of data protection after basic patent expiry
Amisulbrom	6
Benthiavalicarb	3
Cyflufenamid	5
Fenpyrazamine	3
Flubendiamide	5
Fluopicolide	1
Fluoxastrobin	1
Penoxsulam	3
Penthiopyrad	8
Prothioconazole	3
Pyridalyl	9
Spirotetramat	7
Tembotrione	5
Thiencarbazone	4
Valifenalate	5

Source: Enigma Marketing Research report: “New off-patent/generic agrochemicals – post 2015”



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FUNGICIDES

- Azoxystrobin
- Benomyl
- Carbendazim
- Chitosan Oligosaccharides = Plant Vaccine
- Chlorothalonil
- Copper hydroxide
- Copper oxychloride
- Cymoxanil
- Cyproconazole
- Difenoconazole
- Dimethomorph
- Diniconazole
- Epoxiconazole
- Fenoxanil
- Flusilazole
- Flutriafol
- Fosetyl-aluminium
- Hexaconazole
- Imazalil (Sulphate)
- Iprodione
- Kresoxim-methyl
- Mancozeb
- Metaxyl (M)
- Myclobutanil
- Oxadixyl
- Penconazole
- Pencycuron
- Prochloraz (Mn)
- Propamocarb (HCl)
- Propineb
- Propiconazole
- Pyrimethanil
- Tebuconazole
- Thiophanate-methyl
- Thiram
- Triadimefon
- Triadimenol
- Tricyclazole
- Tridemorph
- Zineb
- Ziram

HERBICIDES

- Acetochlor
- Ametryn
- Atrazine
- Benazolin
- Bentazone
- Bispyribac-Sodium

- Bromacil
- Bromoxynil (Octanoate)
- Butachlor
- Clethodim
- Clomazone
- Dicamba
- Diclofop-methyl
- Diflufenican
- Diuron
- 2,4-D series
- Fenoxaprop-P-ethyl
- Fluroxypyr
- Fomesafen
- Glyphosate
- Glufosinate-amonium
- Haloxyp-P-Methyl
- Imazaquin
- Imazethapyr
- Lactofen
- Linuron
- Metribuzin
- Metolachlor
- Nicosulfuron
- Oxadiazon
- Oxyfluorfen
- Paraquat
- Pendimethalin
- Pretilachlor
- Propanil
- Pyrazosulfuron-ethyl
- Quinclorac
- Quizalofop-P-ethyl
- Sethoxydim
- Sulfometuron
- Tralkoxydim
- Trifluralin

SAFENERS

- AD-67
- Dichlormid
- Fenclorim

INSECTICIDES / ACARICIDES / MOLLUSCICIDES

- Abamectin
- Acetamiprid
- Aluminium phosphide
- Amitraz

- (Beta-) Cyfluthrin
- Bifenthrin
- BPMC (Fenobucarb)
- Buprofezin
- Carbaryl
- Carbofuran
- Carbosulfan
- Cartap (HCl)
- Chlorfenapyr
- Chlorfluazuron
- Chlorpyrifos
- (Alpha, Beta) Cypermethrin
- Cyromazine
- Deltamethrin
- Difenthiuron
- Diazinon
- Dichlorvos
- Diffubenzuron
- Dimethoate
- Emamectin benzoate
- Ethoprophos
- Etofenprox
- Fenamiphos
- Fenbutatin oxide
- Fenitrothion
- Fenoxycarb
- Fenpropathrin
- Fenpyroximate
- Fipronil
- Flufenoxuron
- Hexythiazox
- Imidacloprid
- Isoprocarb
- Lambda cyhalothrin
- Malathion
- Metalddehyde
- Methidathion
- Methomyl
- Niclosamide
- Nitenpyram
- Phenthoate
- Pirimiphos-methyl
- Profenofos
- Propoxur
- Propargite
- Pymetrozine
- Pyriproxyfen
- Tebufenozide
- Triazophos
- Trichlorfon

P. G. REGULATORS

- Ethephon
- Gibberellic acid (GA3 / GA4+7)
- Mepiquat chloride
- Paclobutrazol

MIXTURES OF FORMULATION

- Azoxystrobin+Difenoconazole
- Azoxystrobin+Chlorothalonil
- Azoxystrobin+Propiconazole
- Carbendazim+Flusilazole
- Carbendazim+Epoxiconazole
- Carbendazim+Iprodione
- Carboxin+Thiram
- Carboxin+Prochloraz
- Cymoxanil+Mancozeb
- Dimethomorph+Mancozeb
- Hexaconazole+Tricyclazole
- Kresoxim-methyl+Epoxiconazole
- Metaxyl+Mancozeb
- Oxadixyl+Mancozeb
- Oxadixyl+Propineb
- Propiconazole+Difenoconazole
- Propiconazole+Tebuconazole
- Bromoxynil+MCPA
- Butachlor+Propanil
- Pyrazosulfuron-ethyl+Quinclorac
- Abamectin+Acetamiprid
- Chlorpyrifos+Cypermethrin
- Lambda-cyhalothrin+Dimethoate
- Lambda-cyhalothrin+Profenofos
- And others.

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- Amino Acid Fertilizers
- Humic Acid / Fulvic Acid Fertilizers
- Macroelement Fertilizers
- Secondary-element Fertilizers
- Microelement Fertilizers
- Microbial Fertilizers

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