

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA
Alexandria Division

_____)	
TRIANTAFYLLOS TAFAS,)	
)	
Plaintiff,)	
)	
v.)	Case No. 1:07cv846 (JCC/TRJ)
)	
JON W. DUDAS, et al.,)	
)	
Defendants.)	
_____)	

CONSOLIDATED WITH

_____)	
SMITHKLINE BEECHAM)	
CORPORATION, et al.,)	
)	
Plaintiffs,)	
)	
v.)	Case No. 1:07cv1008 (JCC/TRJ)
)	
JON W. DUDAS, et al.,)	
)	
Defendants.)	
_____)	

**BRIEF OF AMICUS CURIAE MONSANTO COMPANY
IN SUPPORT OF PLAINTIFFS' MOTIONS FOR SUMMARY JUDGMENT**

I. Introduction

Monsanto Company (“Monsanto”) respectfully submits this brief in support of the plaintiffs’ motions for summary judgment in the above-captioned consolidated cases. The final rules that the Patent and Trademark Office (“PTO”) published on August 21, 2007, will severely restrict the ability of patent applicants like Monsanto to describe and claim the full scope of their inventions. Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72

Fed. Reg. 46,716 (Aug. 21, 2007) [“Final Rules”] (to be codified at 37 C.F.R. pt. 1). In particular, sections 75 and 265 of the Final Rules, which limit applicants to five independent claims and twenty-five total claims unless the applicant files an “examination support document” (“ESD”) [the “5/25 Rule”], will have adverse and irreparable effects on important types of Monsanto inventions.

The 5/25 Rule, alone and in combination with other provisions of the Final Rules, will result in the forfeiture of patent rights, particularly for those inventions that are generated in an organized program of progressive research and development. In many cases, the Final Rules will prevent inventors from protecting their legitimate interests in their inventions. While the PTO has asserted that applicants can seek to submit more claims by filing an ESD, that is not a viable option because (a) the ESD may unnecessarily sacrifice the legitimate scope of the claims, at a time when the applicant has not fully explored or developed the ultimate market potential of the technology; and (b) the applicant runs the risk that representations made in the ESD will result in claims of inequitable conduct in subsequent litigation.

Monsanto believes that, for numerous reasons, the Final Rules violate patent law and the Administrative Procedure Act. 5 U.S.C. § 706. However, instead of emphasizing those issues, Monsanto addresses the hardships that the Final Rules will cause with respect to companies like Monsanto that typically develop chemical and biological inventions in progressive stages of research. This brief also describes the harm that the 5/25 Rule will cause to the public interest. For the reasons detailed below, the Final Rules are flawed and unjust, and they should be permanently enjoined in full.

II. Background

Monsanto, along with its subsidiaries, is a leading global provider of agricultural products for farmers. The seeds, biotechnology trait products, and herbicides that Monsanto researches,

develops, and brings to market provide farmers with solutions that improve productivity, reduce the costs of farming, produce better feed for animals, and produce better foods for consumers. Monsanto's Seeds and Genomics segment produces leading seed brands, including *DEKALB*®, *Asgrow*®, *D&PL*®, *Deltapine*®, and *Seminis*®, and develops biotechnology seed traits that assist farmers in controlling insects and weeds. Monsanto also provides other seed companies with genetic material and biotechnology traits for their seed brands. Through its Agricultural Productivity segment, Monsanto manufactures herbicide products, including *Roundup*®, for the residential and commercial markets, and provides animal agricultural products focused on improving dairy cow productivity. Monsanto invests heavily in the development and implementation of chemical manufacturing processes for the production of herbicides, including *Roundup*® brand herbicides.

Monsanto spends more than \$2 million per day in research and development to support and improve its businesses. Patents are a critical component of Monsanto's research and development activities and a significant factor in Monsanto's willingness to devote such substantial resources to this work. Particularly relevant here, Monsanto has patents on new formulations and manufacturing processes within its herbicide business, including catalysts that are used in the production of herbicides. In reliance on the availability of adequate patent protection, investment continues in all these technologies.

Biological and chemical products such as those that Monsanto develops typically involve progressive stages of research, sometimes with months going by between obtaining new data (inventions relating to plants obviously must wait for at least one generation of plants to grow). Once the initial invention is made, a patent application claiming it is filed. Additional research, however, often leads to new data, improvements, modifications, and a better understanding of

the invention or of its important properties and the principles on which it functions. New patent claims may be necessary to protect improvements in the developing technology in a scope commensurate with the inventor's contribution to the art. This is particularly important with respect to biological or chemical inventions because, by their nature, they are subject to infinite variation within the scope of the inventive concept by which the art has been advanced. Early in the development process, it is difficult to determine what significance can be placed on certain descriptions of the invention or the importance of alternative ways of describing the same or similar inventions. In addition, a combination of independent and dependent claims is appropriate because, at the time the initial application is filed, the inventor may not fully appreciate which specific combination of features will form the product or process that ultimately will be brought to market, often many years later, or what regulatory hurdles will be faced in bringing the invention to the market. Moreover, during litigation, which may occur years after prosecution, the courts may interpret the claim descriptions differently from what the inventor intended, adding to the importance of presenting a full claims set.

Each claim in a patent application defines inventive subject matter that differs from every other claim. All of the claims together define the subject matter to which the inventor is entitled. Applicants must present all patentable claims during original prosecution because claims cannot be added or amended in litigation, and adding or amending claims after the patent has issued is difficult, risky, and constricted by law. Accordingly, selection of which claims to present in prosecution determines the inventor's rights in his or her invention.

The key flaw in the 5/25 Rule is that it improperly limits an inventor's ability to protect the full scope of the invention by preventing the inventor from submitting an appropriate combination of independent and dependent claims. Broad independent claims may be vulnerable

to assertions that they are not novel, or that they are obvious from prior art.¹ Narrower dependent claims—which are more specific and contain more limitations—may avoid these potential issues, but they are unlikely to cover all embodiments of an invention to which an inventor is entitled.²

Applicants properly seek to address these concerns by submitting multiple independent (*i.e.*, broader) claims to provide breadth of coverage and multiple dependent (*i.e.*, narrower) claims to provide both depth of coverage and a finely graduated scope of protection. As development of an invention progresses, applicants need the ability to claim additional embodiments of the invention disclosed in the initial application, as well as improvements and new uses that are patentable over prior art. A properly structured series of claims is important to avoid gaps in patent coverage that would undermine the legitimate interests (and investment) of the patent holder. Such gaps may enable a competitor to appropriate the essence of the invention by designing around the claims, without having invested in the original research, because subject matter disclosed in a patent application but not claimed is in the public domain. In a complex technology, such gaps likely are unavoidable if the claim structure of even a single application is limited to twenty-five claims.

¹ Even when a patent examiner determines the validity of such claims during prosecution, they are at risk of being found obvious in light of prior art in the after-the-fact judgment of a court or jury during litigation, especially where prior art surfaces that has not been identified in prosecution. On the ultimate issue of obviousness, newly discovered prior art can properly render a broad independent claim obvious without similar effect on a slightly narrower dependent claim or even a parallel independent claim that is narrower with respect to features to which the reference is relevant but broader in other respects.

² An independent claim could recite “salt” and a dependent claim could recite “sodium chloride.” If the prior art were potassium chloride, the independent claim could be invalidated, but not the dependent claim. However, the dependent claim fails to cover other salts that the inventor could be entitled to other than sodium chloride.

Many of the inventions that the 5/25 Rule will adversely affect are capable of trade secret protection. Accordingly, when possible, inventors and their assignees may opt to treat their inventions as trade secrets instead of seeking the less robust patent protection that will result if the 5/25 Rule is implemented. Should this occur, the public interest would suffer as a result of the lack of public disclosure of these inventions.

The adverse consequences of the 5/25 Rule are best illustrated by an example taken from one of Monsanto's developing catalyst technologies.

III. Catalyst Technology: An Example of the Severe Adverse Effects of the 5/25 Rule

A. Claiming Novel Catalysts

A catalyst is a substance that increases the rate of a chemical reaction without itself being consumed. While different catalyst structures often have similar compositions, they can have vastly different molecular mechanisms of action.³ Catalysts are important during manufacture of many commercially produced chemical products, such as methanol, ammonia, and sulfuric acid. Through its research, Monsanto looks for better and more economical ways to produce chemical products by developing new catalysts.

Because describing the composition of a catalyst generally is not the best way of enabling others to practice the invention, the patent specification of a novel catalyst usually describes a method of its preparation and its physical properties. However, when first developed, many details of the catalyst's characteristics remain unknown, and the exact composition of the active sites may defy precise analysis for a long period of time. Thus, from necessity, novel catalysts often are redefined over time based upon the identification of physical properties that are

³ For example, one mechanism that increases the rate of a chemical reaction involves bringing the reactants in closer proximity to each other by having them both bind to "active sites" of the catalyst.

associated with the catalyst's performance in a catalytic reaction. These physical properties involve or relate to such complex subjects as specific surface area, sorption and desorption characteristics of the catalyst surface, solid state phase relationships at active sites, physical microstructure of the catalyst, and electronic configuration of the catalyst. While there are many ways to assess a catalyst, in the early stages of development it is difficult to know which properties are important or even the most effective way to define the catalyst's relevant properties.

Thus, to fully describe and claim novel catalysts, the patent applicant must be able to make a claim for each property of the catalyst associated with favorable or commercially important catalytic performance. But the relationship of performance to composition, microstructure, or properties must be determined by doing expensive and time-consuming research. The inventor is able to completely protect the invention only through separate claims covering various properties associated with performance and details of the catalyst's microstructure. Otherwise, because a catalyst is relatively inexpensive to make, parasitical competitors can easily follow the teaching of the patent application while designing around all of the claimed properties and details. Only when many broad and narrow claims are presented to claim properties separately and in different combinations will the patentee be able to derive an appropriate scope of protection to reward his or her investment in the invention.

The ability to fully claim novel catalysts is essential to reliable patent protection of catalyst technology, but will be frustrated by the 5/25 Rule. In some instances, catalysts are subject to preservation as trade secrets. In those cases, the imposition of the 5/25 Rule will precipitate a major trend in the direction of secrecy, or the diversion of funds from catalyst research, thereby frustrating the rate of progress in this commercially important art.

B. Monsanto's Oxidation Catalyst Technology

Monsanto has been conducting research to reduce the expense of producing an important herbicide for farmers. Production of the herbicide uses an oxidation catalyst comprising a composition on a carbon support. This is an expensive ongoing research project and, so far, there have been at least three generations of progressive development.

Applications directed to the first generation of this technology are still pending.⁴ They include claims directed to catalysts comprising various transition metal and nitrogen compositions on a carbon support, and the use of these catalysts in the oxidation of organic substrates such as aldehydes, ketones, acids, and amines. Included are claims that define the transition metal composition as a cobalt nitride, cobalt carbide nitride, iron nitride, or iron carbide nitride.⁵

The second generation application also claims a process that uses oxidation catalysts on various carbon supports. But the oxidation catalyst is described in terms of various specific surface area parameters⁶ and combinations thereof that are also based on generally less expensive non-noble metals,⁷ thereby enabling millions of dollars to be saved in making a herbicide.

⁴ U.S. Patent Application Publication No. 2005/0176990 (published Aug. 11, 2005); U.S. Patent Application Publication No. 2006/0068988 (published Mar. 30, 2006). One patent related to this catalyst technology has issued, U.S. Patent No. 7,129,373 (issued Oct. 31, 2006) (the '373 patent). The original priority date of these applications and patent is February 14, 2002.

⁵ The '373 patent also includes claims to a catalyst comprising a noble metal deposited over a modified carbon support having a transition metal/nitrogen composition thereon. Noble metals are resistant to corrosion or oxidation. They include precious metals, such as gold, silver, tantalum, platinum, palladium, and rhodium.

⁶ These parameters include such highly technical subjects as total Langmuir surface area, mesopore surface area, micropore surface area, and comparisons of Langmuir surface area parameters of the catalyst with those of the support.

⁷ Non-noble metals on which the Monsanto catalysts are based are transition metals that are generally much less expensive than the precious metals. The first independent claim describes

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The third generation application⁸ claims a novel method for preparing further improved catalysts, and contains multiple independent claims separately characterizing the improved catalyst in terms of physical properties different from the properties claimed in the second generation application.⁹ The third generation claims more finely define the invention by including in the claims a list of preferred transition metals for the carbon support.¹⁰

If the Final Rules are given effect, the PTO will apply the 5/25 Rule to applications filed before November 1, 2007, in which a first Office action on the merits was not mailed before that date. 72 Fed. Reg. at 46,716. The 5/25 Rule therefore would apply to all three generations of these Monsanto applications, despite the fact that they were filed before the Final Rules were published. Because it has already filed these patent applications, Monsanto cannot keep this technology as a trade secret. Indeed, U.S. Patent Application Publication Nos. 2005/0176989, 2005/0176990, 2006/0068988, and 2006/0229466 have published and are available to the public.

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an oxidation catalyst as comprising “a carbon support having formed thereon a transition metal composition . . . wherein the total Langmuir surface area of said catalyst is at least about 60% of the total Langmuir surface area of said carbon support prior to formation of said transition metal composition thereon.” U.S. Patent Application Publication No. 2005/0176989 (published Aug. 11, 2005).

⁸ U.S. Patent Application Publication No. 2006/0229466 (published Oct. 12, 2006) (the ‘466 publication).

⁹ These include: (i) time of flight secondary ion mass spectrometry (“ToF SIMS”); (ii) particle size of the transition metal/nitrogen composition on the carbon support; (iii) x-ray photoelectron spectroscopy (“XPS”); and (iv) electron paramagnetic resonance (“EPR”).

¹⁰ The first independent claim of the ‘466 publication recites “a catalyst, wherein the catalyst comprises a carbon support having formed thereon a transition metal composition comprising a transition metal (M) and nitrogen, the transition metal being selected from the group consisting of copper, silver, vanadium, chromium, molybdenum, tungsten, manganese, cobalt, nickel, cerium, and combinations thereof, wherein the catalyst is characterized as generating ions corresponding to the formula $MN_{x}C_{y}^{+}$ when the catalyst is analyzed by Time-of-Flight Secondary Ion Mass Spectrometry (ToF SIMS) as described in Protocol A and the relative abundance of ions in which x is 1 is at least 20%.”

These three generations of applications include 39 independent claims and 233 total claims. The total is relatively low because many of the independent claims have not yet been further detailed with a full series of appropriate dependent claims. To adequately cover this technology through the first three generations will ultimately require 500 to 1,000 claims. The independent and dependent claims in the first generation application play a different role in protecting the invention from the independent and dependent claims in the third generation application. To the extent that the number of claims is arbitrarily reduced, Monsanto will incur increased risk of leaving a gap and not covering an invention that it is otherwise entitled to claim. A competitor that has not made the investment in research may exploit this gap to Monsanto's detriment.

IV. The Final Rules Will Result in the Forfeiture of Patent Claims

A. Forfeiture Under the 5/25 Rule

As described above, the application of the 5/25 Rule will likely restrict Monsanto's ability to fully define and claim its novel oxidation catalyst in a manner consistent with Monsanto's contribution and investment. The 5/25 Rule as applied among claims of different applications containing patentably indistinct claims is especially prejudicial, with the greatest prejudice suffered by research-based companies like Monsanto. As described above, progressive research requires a series of successive patent applications. Many narrower subgeneric and species claims in the second generation application include limitations not present in the first generation, but fit within a broader genus claim in the earlier application. The third generation application includes additional subgeneric claims, as well as species claims, within the scope of both of the earlier applications. In these circumstances, regardless of whether each of the second and third generation applications is patentable over its predecessor application, the 5/25 Rule will be applied against the entire family of copending applications, thereby limiting the inventor to a

sum of five independent claims and twenty-five total claims to be allocated among the several applications.¹¹

The 5/25 Rule also would prevent Monsanto from claiming additional embodiments or properties of its novel catalyst beyond those already claimed. The Final Rules may force Monsanto either to reduce these current applications, among all three generations, to a total of five independent claims and twenty-five total claims or to file an ESD.

B. The Examination Support Document Option Is Impractical and Unreasonable

The Final Rules provide that the 5/25 Rule limitation can be relaxed, but only if the applicant files an ESD prior to the first Office action on the merits. The availability of this option is an illusion. The ESD protocol requires that the applicant search all U.S. patents and patent application publications, all foreign patent documents, and all non-patent literature, covering all claim limitations. Final Rule 265(b). For each material reference, the applicant must identify all the limitations of each claim that are shown by the reference and explain how each claim is patentable over the reference. Final Rule 265(a)(3)-(4). And, there must be a further showing of where each limitation of each claim finds support in the applicant's specification. Final Rule 265(a)(5). The cost of all of this will be prohibitive.¹²

¹¹ Under 35 U.S.C. § 103(c), the earlier generation applications are often disqualified as prior art to later generation applications for purposes of obviousness under 35 U.S.C. § 103(a). But as discussed below, the benefit of § 103(c) is nullified by the 5/25 Rule. Even in later generation applications that qualify as patentable over earlier applications under § 103(a) as applied by the Supreme Court in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), and *KSR International Co. v. Teleflex Inc.*, ___ U.S. ___, 127 S. Ct. 1727 (2007), there is no relief from the 5/25 Rule. In the Monsanto example, the PTO cannot apply the first generation applications as prior art against the second, nor the second against the third under § 103(c). The third generation application is believed to be patentable as non-obvious over the first under § 103(a), but that does not avoid the 5/25 Rule since claims of the first generation applications read on or are obvious from the third.

¹² The Final Rules provide an exemption for small entities from the requirement that an ESD must, for each reference cited, identify all the limitations of each of the claims that are disclosed

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Moreover, an attempt to comply with Rule 265 puts the applicant in the position of making statements that may not facilitate prosecution or even respond to as yet unknown concerns of the examiner. Having to make such statements in a vacuum could lead the applicant to characterize both the claims and the prior art in a manner that is at best unhelpful to the examiner and at worst could later be used as the basis for unwarranted fraud allegations in litigation, expanding the current plague of such allegations. Indeed, if the examiner finds the applicant's ESD unhelpful or if the claims change after submission of the ESD, the examiner could ask the applicant any number of times to supplement the record, increasing the cost to the applicant and the time spent by both the applicant and the examiner in prosecution.

Thus, the applicant is faced with a Hobson's choice: either undertake the expense and untoward risks of submitting an ESD; or be relegated to the restrictions of the 5/25 Rule. The only escape from this dilemma is to preserve complex technologies as trade secrets, if and when that is possible.

C. The Forfeiture of Claims Is Amplified by Other Provisions of the Final Rules

The forfeiture of claims arising from the 5/25 Rule is amplified by the Final Rule's limit of no more than two continuation or continuation-in-part applications. Under the 5/25 Rule and current continuation practice, an applicant could, at least in theory, pursue all of its patentable claims by filing a series of twenty-five-claim continuation applications—albeit at exorbitant expense, after extended delay, and probably with significant loss of patent term. But under the Final Rule's limitations on continuation practice, even this unattractive alternative is not available, because only two continuation or continuation-in-part applications are allowed.

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by the reference. Final Rule 265(f). This exemption suggests that the PTO recognizes the extreme burden involved in submitting an ESD.

Thus, the combination of these two rules limits an applicant to a maximum of fifteen independent and seventy-five total claims, in the original application and the two permitted continuation or continuation-in-part applications, and then only if there are no patentably indistinct claims in copending continuing applications. If there is even one patentably indistinct claim in a copending continuing application, all of the claims in that continuation or continuation-in-part application and all of the claims of the original application must be within the 5/25 Rule.

The only way to get more than twenty-five claims examined at one time, other than filing an ESD, is to file a divisional application. Divisional applications can be filed in parallel with a continuation or continuation-in-part application, but can only contain claims that the PTO previously has found to be patentably distinct from all other claims in copending applications. Because only the PTO can find the claims patentably distinct for purposes of a divisional application, divisional applications would be permitted only for claims previously presented in an initial application or one of the two continuation or continuation-in-part applications.

By limiting the divisional applications to previously presented claims, the 5/25 Rule limits the subject matter that can ever be presented to subject matter within the scope of only the patentably distinct claims filed in the original application and its two continuation or continuation-in-part applications. There is no way to have claims examined in a separate application, even if they are patentably distinct, without the PTO first confirming that they are patentably distinct. This hobbles the presentation of new claims directed to different aspects of an invention as continued research determines that such aspects are important to a commercial embodiment of the invention.

If even one of any of a set of new claims is found patentably indistinct from even one copending claim, and twenty-five claims are already present among the pending applications, an applicant would have to cancel a pending claim to compensate for each claim added, or wait to file a continuing application until one of the copending applications is allowed or abandoned. Under the Final Rules, a divisional application is allowed two continuation applications, provided the claims remain within the same scope as the claims originally presented in the divisional application. But any such divisional application and any continuation applications thereof would also be limited to five independent claims and twenty-five total claims among them unless the divisional application and its continuation applications are prosecuted serially with consequent sacrifice in term.

While continuation applications can be filed from divisional applications, continuation-in-part applications cannot. Final Rule 78(d)(1)(iii). Later developed data that support a “distinct” invention can be incorporated only as a continuation-in-part application of the original application (assuming one remains available). If the original application is not pending, the new data cannot be incorporated as a continuation-in-part application.

V. Other Principles of Patent Law Prevent Remediating the Harm Caused by the 5/25 Rule

A. Further Restriction of the Doctrine of Equivalents

If a competitor takes advantage of a gap in patent coverage caused by the 5/25 Rule and each part of the competitor’s design-around has only an “insubstantial change” compared to each part of the claimed invention, the patent holder can argue that there is infringement even if the design-around does not fall within the express terms of a patent claim. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39-40 (1997). However, in recent years, the courts

have progressively constricted this doctrine, referred to as the doctrine of equivalents, and these restrictions exacerbate the adverse effects of the 5/25 Rule.

1. Prosecution History Estoppel

Under the landmark *Festo* decisions,¹³ essentially any amendment during prosecution that adds a claim element or narrows an existing element, and that relates to a substantial issue of patentability, creates a risk of an estoppel against the enforcement of the claim under the doctrine of equivalents with respect to that element.¹⁴ If the competitor offers a product or uses a process that substitutes an equivalent for the added or narrowed element, the claim cannot be enforced under the doctrine of equivalents if the substitution would have been “foreseeable” at the time the application was filed.

Thus, instead of relying on the doctrine of equivalents, it is critical to enforcement for the patentee to have claims in the original patent that can be literally read on any foreseeable competitive product or process. According to longstanding patent practice in complex technologies, this need typically is met by presenting a relatively large number of claims, including parallel claims that may omit the narrowed element of the amended claim, while distinguishing the prior art in other ways that a competitor may not ultimately avoid.

The 5/25 Rule will severely limit the number of claims of varying scope that can be prosecuted, even where the impact is not compounded by applying the Rule against the sum of claims in related applications. Moreover, if a claim that would literally cover the accused product or process is present in the application as filed, or in a foreign counterpart or PCT

¹³ See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), and its Federal Circuit progeny.

¹⁴ Moreover, there is a presumption that any narrowing amendment does relate to a substantial issue of patentability. See *Festo*, 535 U.S. at 739-41.

application where claim limitations do not apply, “foreseeability” will be conclusively established and enforcement under the doctrine of equivalents barred by *Festo*.

2. Inadvertent Dedication

Even in the absence of an estoppel, application of the doctrine of equivalents can be barred by inadvertent dedication of subject matter that is disclosed but not claimed. *See Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002). For example, if the broadest claim is found unpatentable over previously unidentified prior art, the 5/25 Rule may leave gaps in coverage that may enable a competitor to resort to the patentee’s own teachings in developing a competing technology that avoids the remaining valid claims.

B. Inadequate Post-Issue Remedies; Intervening Rights

Under the patent laws, competitors that choose not to invest in research can legitimately try to appropriate the value of patented inventions by designing around valid claims or finding additional prior art. In anticipation of such competitive activity, inventors seek to develop an adequately graduated claim structure and, where possible, to add claims supported by their pending applications that read on competitors’ products as they emerge in the market place. This response is consistent with patent law.¹⁵

But after all applications based on a given disclosure have issued, the only alternative currently available for changing or adding claims to remedy any discovered gaps involves returning to the PTO for remedial prosecution, either re-examination under 35 U.S.C. § 302 or re-issue under 35 U.S.C. § 251. If a change or addition is pursued at that time, the patent holder can suffer significant prejudice against enforcement and further time delay. For example, unless

¹⁵ *See Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988). In defending the new rules as prohibiting the practices expressly authorized by *Kingsdown* (on grounds of notice or otherwise), certain *amici* essentially are admitting that the new rules improperly alter existing law.

an original claim that reads on a competitor's product or process is upheld during remedial prosecution, the patent holder cannot recover damages for the period prior to the date that a revised patent or certificate issues.¹⁶ This is so even if a claim added in the remedial PTO proceeding covers the infringer's product and is determined to be valid by a court. *See BIC Leisure Prods.*, 1 F.3d at 1220-21. Also, if the claims are amended, the court can allow a competitor to continue infringing activity in certain circumstances where the competitor relied on an error in the original claims. 35 U.S.C. § 252.

To avoid these problems in litigation, longstanding patent practice in complex technologies involves presenting a relatively large number of claims that aim to distinguish the prior art and prevent a competitor from copying the invention. However, as discussed above, the 5/25 Rule, alone and in combination with other provisions of the Final Rules, will severely limit the ability of patent applicants to prosecute a sufficient number of claims to provide insurance against these types of risk.

C. Evisceration of the Protection of 35 U.S.C. § 103(c)

Congress enacted § 103(c) of the Patent Act in 1984 and expanded it in 1999 to overrule the adverse effect on organized research of the decision of the Court of Customs and Patent Appeals in *In re Bass*, 474 F.2d 1276 (1973). *See Oddzon Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1402-03 (Fed. Cir. 1997) (discussing history and purpose of 35 U.S.C. § 103(c)); *Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co.*, 973 F.2d 911, 917 (Fed. Cir. 1992) (same). Section 103(c) prevents inventions made in the course of organized research from being held unpatentable as obvious from earlier inventions, disclosures, and patent applications

¹⁶ This legal principle is referred to as intervening rights. *See BIC Leisure Prods., Inc. v. Windsurfing Int'l, Inc.*, 1 F.3d 1214, 1220-21 (Fed. Cir. 1993); *Fortel Corp. v. Phone-Mate, Inc.*, 825 F.2d 1577, 1579-80 (Fed. Cir. 1987).

produced in the same organization that qualify as prior art under § 102(e), § 102(f), or § 102(g). Congress recognized that applying such art for purposes of obviousness under § 103(a) would disqualify meritorious inventions arising from the typically progressive nature of organized research, while discouraging the communication and collaboration among co-workers that is the lifeblood of a research organization.

The 5/25 Rule as applied among multiple applications effectively defeats the purpose of § 103(c). In a series of commonly owned applications respectively directed to successive generations of development in a given technology, § 103(c) cannot afford relief where the 5/25 Rule imposes a drastic limit on the number and scope of claims that can be filed. If multiple generations of applications remain copending, the inventor will have difficulty in presenting any claims at all in a fifth, fourth, or even third generation application without exceeding the 5/25 limit. Thus, the benefits otherwise available from § 103(c) are rendered nugatory.

VI. Conclusion

Given the unjustified prejudicial impact of the 5/25 Rule on valuable research, especially when combined with other provisions of the Final Rules, Monsanto respectfully submits that the rule is fundamentally unfair and unreasonable. Furthermore, the 5/25 Rule will also compel inventors wherever possible to secrecy, thus impairing the progress of the useful arts. Because of the breadth and complexity of the 5/25 Rule, and the Final Rules generally, only a permanent injunction against this entire scheme will preserve the efficacy of the patent laws as Congress intended.

Respectfully submitted,

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December 27, 2007

CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of December 2007, I caused a copy of the foregoing Brief of *Amicus Curiae* Monsanto Company in Support of Plaintiffs' Motions for Summary Judgment to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send a notification of such filing to the following:

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