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BIOTECHNOLOGY COMMERCIALIZATION

PROFESSOR GRANT ISAAC

INTELLECTUAL PROPERTY RIGHTS PROFILE: SOMATIC EMBRYOGENESIS

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Introduction

Westvaco Corporation was one of the member companies in the $60 million 1999 joint venture between Monsanto, Fletcher Challenge Forests and International Paper. The commercial venture of the application of intellectual property created from this partnership is embodied in ArborGen™ where the commercialization of their patented SE processes and technologies are applied primarily to loblolly pine regeneration.

Somatic Embryogenesis (SE) is detailed in several patent claims as it applies to targeted species of plants and trees. Also, several products relating to the support of SE processes are claimed, such as a culture for storing the gymnosperm plasma or a solution for activating the cellular recovery process after storage. The patent most relevant to ArborGen™ commercial application details their process, and some associated cultures and equipment, for generating a gymnosperm of targeted species of pine trees.

Background and Patent Search

The United States Patent and Trademark Office (USPTO) maintain an online searchable database for all existing patents. A search of the registered patents with the USPTO from 1976 to present for conifer (coniferous, conifers) AND somatic AND embryogenesis showed a listing of 70 patents. These 70 patents are all claimed on certain processes and products related to the application of somatic embryogenesis on conifers.

These 70 patents are held by corporations or individuals primarily in Canada and the United States at the research level of corporations or University research institutions although there are a few individuals that have received successful claims. These corporations and individuals are summarized in Table 1[1].

Table 1 – Summary of Patent Assignees relating to Conifer SE

Number of Patents Held	Corporation or Individual
19	Weyerhaeuser Company (Federal Way, WA)
13	Westvaco Corporation (New York, NY)
4	Cellfor Inc. (Vancouver, CA)
3	Union Camp Corporation (GA/NJ/IL/PA)
3	North Carolina State University (Raleigh, NC)
2	Rutgers, State University of New Jersey
2	Institute of Paper Science & Technology (Atlanta, GA)
2	Attree; Stephen M. (Victoria, British Columbia, CA) – Now at the U of S
2	Carter Holt Harvey Limited (Manukau, NZ)
2	University of Saskatchewan (Saskatchewan, CA)
2	University of California (Oakland, CA)
1	Secretary of Agriculture (US)
1	Dekalb Genetics Corp. (Mystic, CT)& Cornell Research Foundation, Inc. (Ithaca, NY)
1	Ministry of Forests (Victoria, CA) Her Majesty the Queen in right of Canada, as represented by the Minister (Ottawa, CA)
1	Pioneer Hi-Bred International, Inc. (Des Moines, IA)
1	Agriculture and Agri-Food Canada (Ontario, CA)
1	University of Kentucky Research Foundation (Lexington, KY)
1	Edmonds; Timothy Kent &Cervelli; Robert Leo Halifax, Nova Scotia, CA
1	University of Hawaii at Manoa (Honolulu, HI)
1	Ohio State Research Foundation (Columbus, OH)
1	Wisconsin Alumni Research Foundation (Madison, WI)
1	University of Tennessee Research Corporation (Knoxville, TN)
1	New Zealand Forest Research Institute Limited (Rotorua, NZ)
1	Unilever Patent Holdings B.V. (Vlaardingen, NL)
1	Gupta; Pramod K. & Pullman; Gerald S. (Federal Way, WA)
1	Forgene, Inc. (Rhinelander, WI)
1	British Columbia Research Corporation (Vancouver, CA)
70	

A further patent search of Westvaco Corporation, as assignees of patents, found 805 instances where Westvaco Corporation has established patent claims with USPTO, primarily on industrial processes and biotechnology products relating to paper manufacturing and forestry.

This same search of conifer related SE conducted with the Canadian Intellectual Property Office (CIPO) revealed 8 listed patent results; four for Weyerhaeuser, three for Westvaco Corporation, one for Carter Holt Harvey Ltd. and one for the New Zealand Forest Research Institute. Upon further research, these eight patents seem to be the most pivotal patents that create claim space around the application of SE to conifers.

The first patent registered with USPTO regarding SE and forest tree reproduction is Embryogenesis of gymnosperm forest trees (#36623) granted to Gupta et al. of Weyerhaeuser Company on May 7, 1979.[2] Gupta et al. of Weyerhaeuser also holds the earliest patent for SE directly relating to conifer application entitled Method for reproducing coniferous plants by *somatic embryogenesis* (#321035) filed on March 9, 1989 and accepted on September 18, 1990.[3] The first Westvaco patent was filed on Method for regeneration of coniferous plants by *somatic embryogenesis* (#138994) on October 21, 1993.[4]

Patent Rules

The patent process follows predefined courses of logic in the examination of validity for patents. This process has been summarized in Table 2 for its specific application to conifer SE, the focus of Westvaco's primary commercial patent.

Table 2 – Patent Process relating to Conifer SE

Patent Rule	In Relation to Conifer SE
Invention	- satisfied by detailing an *improved art* over the SE process as it specifically relates to the targeted pine species noted in the claim.
Novelty	- satisfied by ensuring the invention was not disclosed to the public prior to October 21, 1988.
Inventive Ingenuity *Non-obviousness*	- satisfied by stipulating specific process conditions and methods of the SE process that *sufficiently improve* the previous Weyerhaeuser claim.
Utility	- satisfied by ensuring purpose of the invention is explicitly detailed in the claim. It is assumed the firm would have taken steps to enact the claim independently. The process is now in commercial use.
Sufficiency of Disclosure	- satisfied by explicitly detailing all process methods and conditions so that diffusion of knowledge occurs.
Unity of Invention	- satisfied by focussing solely on the conditions and methods surround SE on targeted pine species. Other patented products and processes used for this claim are detailed in the patent.
Research Exemptions	- research was created under a privately funded partnership. Westvaco must allow research exemptions where royalties are waived.
Public Order and Morality	- public and legal stance on forest biotech products has yet to be resolved.

Patent Duration

Westvaco's patent on the process of SE on targeted pine species is due to expire on October 22, 2013. Other Westvaco patents on related processes and products of conifer SE expire between 2013 and 2023. So it is evident that they are continuing to invest in research and development of knowledge and translate that into patent claim. While this technology is new and there are few firms with the capacity to explore variations of the claim, an incremental protection strategy could be considered where Westvaco continues its research and development activities regarding optimizing the results and enhancing the process so that another patent may be claimed after 2013. This patent would have to satisfy the rules, as previously explored, but this strategy could provide the opportunity for product control and return on investment.

Patent Breadth

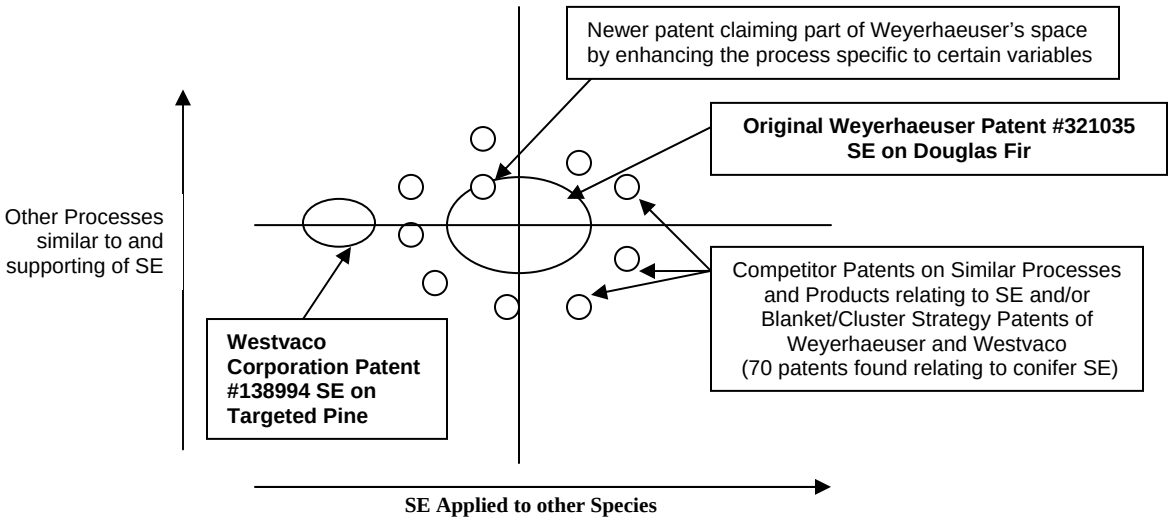
The ArborGen™ claim over somatic SE seems partially shared by Weyerhaeuser as well as several other organizations and individuals. The plethora of patents surrounding SE are in place for three strategic reasons:

1. Fencing – vertical patent space is claimed surrounding a central patent claim. i.e. The main patent of the process for somatic embryogenesis on loblolly pine, so a new patent is also claimed other processes and products similar to and supporting of SE;
2. Blanketing – horizontal patent space is claimed surrounding the central patent claim. i.e. The main patent of the process for somatic embryogenesis on loblolly pine, so a new patent is also claimed for the SE process to be applied to other species;
3. Clustering – utilizing both a fencing and blanketing strategy to protect your patent claim space. i.e. Protecting your main patent of somatic embryogenesis on loblolly pine by claiming patent space on somatic embryogenesis processes for all species and other processes and products similar to and supporting of SE.

Westvaco's patent #138994 details the main commercial application used by ArborGen™. While Weyerhaeuser's original patent details the application of SE to Douglas Fir, their second patent is a more general application regarding the process rather than the species application. It's primary claim is that 'the method has been successful with a broad range of species and with numerous genotypes that could not previously be propagated by embryogenesis'. Westvaco's patent extensively cites Gupta et al. and the previous work done by Weyerhaeuser and is very specific about the claims on specific solutions and actions involved in the process that provide adequate novelty and non-obviousness from Weyerhaeuser's claims. Westvaco's patent details the application of SE to loblolly pine, specifically the species Pinus taeda, Pinus serotina, Pinus palustris, Pinus elliottii, Pinus rigida, and hybrids thereof.

The amount of patent "claim space" is modelled in Figure 1. A more thorough understanding of the exact application of certain scientific principles noted in each patent is required to detail the exact claim space, but presence analysis shows that Weyerhaeuser and Westvaco hold the majority of claim space on somatic embryogenesis as it relates to conifer applications and targeted species.

Figure 1. Estimation of Claim Space over Somatic Embryogenesis



Patent Costs

Westvaco holds over 800 patent claims, with 13 claims specifically to conifer SE. And while it is difficult to accurately estimate the costs of filing and maintaining these patents for Westvaco, clearly doing so is a part of their core competencies and adds value to their firm. The costs for patents specific to Westvaco and conifer SE are summarized in Table 3.

Table 3 – Patent Cost Estimates for Westvaco Corporation

Patent Cost	Per Patent	All 805 Patents	All 13 Patents relating to Conifer SE
Fixed Costs			
Patent Searches	$5,000	$4,025,000	$65,000
Application Development	$5,000 to $40,000*	$20,000,000+	$150,000+
Application Fees	$3500 to $5000	$2,800,000 to $4,025,000	$45,500 to $65,000
Revision Fees	$1000 to $4000	$805,000 to $3,200,000	$13,000 to $52,000
Maintenance Fees	$1200/year	$966,000	$15,600
Variable Costs			
Monitoring	$1000/year	$805,000	$13,000
Defending	Unknowable	-	-
Estimated Totals		**~$30,000,000+**	**~$335,000+**

*Range based on the costs for professional time to enact the claim, develop the application, and ensuring full disclosure. In some cases the claim is a new utility for an existing invention, which may not require as extensive a documentation and enactment process as something wholly novel.

Westvaco Corporation's Cost of Sales, which includes their costs for patent management, were $6.2 billion with Net Sales of $7.24 billion and a Net Loss of $389 million for fiscal 2003.[5] If these estimates prove accurate, Westvaco would be spending approximately 3.3% of their cost of goods sold on their patent management, or 2.7% of sales.

Patent Strategy

With such massive investments in intellectual property and patent claims, Westvaco Corporation will want to ensure it maintains this into the future. Creating new knowledge is clearly one of their core competencies and Westvaco will want to ensure this knowledge is both protected and accounted. They will want to consider incremental protection strategies, such as the significant enhancement in methods and conditions of conifer SE to create utility and novelty for a new patent that can be established after 2013. They will also want to monitor the industry to both ensure their knowledge is being used with proprietary regard and to see where new advancements and applications are being claimed.

References

[1] http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&u=%2Fnetahtml%2Fsearch-adv.htm&r=0&f=S&l=50&d=PTXT&RS=conifer&Refine=Refine+Search&Refine=Refine+Search&Query=conifer+and+somatic+and+embryogenesis – USPTO Patent Listing

[2] http://patft.uspto.gov/netacgi/nph-Parser?Sect2=PTO1&Sect2=HITOFF&p=1&u=%2Fnetahtml%2Fsearch-bool.html&r=1&f=G&l=50&d=PALL&RefSrch=yes&Query=PN%2F4217730 – Weyco Original Patent on Douglas Fir

[3] http://patft.uspto.gov/netacgi/nph-Parser?Sect2=PTO1&Sect2=HITOFF&p=1&u=%2Fnetahtml%2Fsearch-bool.html&r=1&f=G&l=50&d=PALL&RefSrch=yes&Query=PN%2F4957866 – Weyco Secondary Patent

[4] http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&u=/netahtml/search-adv.htm&r=57&f=G&l=50&d=PTXT&p=1&p=2&S1=((conifer+AND+somatic)+AND+embryogenesis)&OS=conifer+and+somatic+and+embryogenesis&RS=((conifer+AND+somatic)+AND+embryogenesis) – Westvaco Corporation patent

[5] http://www.meadwestvaco.com/corporate.nsf/investor/financialReports - Meadwestvaco Corporation